FEDERAL TRADE COMMISSION

I N D E X (PUBLIC RECORD)

| | | |
|---|---|---|
| 1 | Commission | |
| 2 | CX 1090 | 3952 |
| 3 | Schering | |
| 4 | SPX 250 | 4048 |
| 5 | SPX 331 | 3941 |
| 6 | SPX 1096 | 3920 |
| 7 | Upsher | |
| 8 | USX 189 | 3976 |
| 9 | USX 281 | 3940 |
| 10 | USX 329 | 3926 |
| 11 | USX 342 | 3960 |
| 12 | USX 361 | 3980 |
| 13 | USX 538 | 3966 |
| 14 | USX 727 | 3979 |
| 15 | USX 1041 through 1145 | 3917 |
| 16 | USX 1146 through 1266 | 3917 |
| 17 | USX 1179 | 3917 |
| 18 | USX 1188 | 3985 |
| 19 | USX 1190 | 3986 |
| 20 | USX 1192 | 3986 |
| 21 | USX 1216 | 3987 |
| 22 | USX 1226 | 3987 |
| 23 | USX 1235 | 3988 |
| 24 | USX 1258 | 3990 |
| 25 | USX 1260 | 3990 |

| | | |
|---|---|---|
| Upsher | | |
| USX 1263 | | 3991 |
| USX 1265 | | 3992 |

FEDERAL TRADE COMMISSION

| | |
|---|---|
| In the Matter of: | ) |
| SCHERING-PLOUGH CORPORATION, | ) |
| a corporation, | ) |
| and | ) |
| UPSHER-SMITH LABORATORIES, | ) File No. D09297 |
| a corporation, | ) |
| and | ) |
| AMERICAN HOME PRODUCTS, | ) |
| a corporation. | ) |
| ---------- | ) |

Friday, February 15, 2002

9:30 a.m.

TRIAL VOLUME 17

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:

KAREN G. BOKAT, Attorney
PHILIP M. EISENSTAT, Attorney
MELVIN H. ORLANS, Attorney
SETH C. SILBER, Attorney
Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2912

ON BEHALF OF SCHERING-PLOUGH CORPORATION:

JOHN W. NIELDS, Attorney
LAURA S. SHORES, Attorney
MARC G. SCHILDKRAUT, Attorney
JASON RAOFIELD, Attorney
Howrey, Simon, Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402
(202) 783-0800

ON BEHALF OF UPSHER-SMITH LABORATORIES:

ROBERT D. PAUL, Attorney
J. MARK GIDLEY, Attorney
CHRISTOPHER M. CURRAN, Attorney
PETER CARNEY, Attorney
White & Case, LLP
601 Thirteenth Street, N.W.
Suite 600 South
Washington, D.C. 20005-3805
(202) 626-3610

ON BEHALF OF AMERICAN HOME PRODUCTS:

BARBARA H. WOOTTON, Attorney
Arnold & Porter
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5667

P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: Good morning, everyone.

ALL COUNSEL: Good morning, Your Honor.

JUDGE CHAPPELL: Back on the record, 9297.

Who's first?

MR. NIELDS: Your Honor, the witness for today will be Dr. Halvorsen. He's an Upsher witness. As I think I mentioned earlier, Mr. Audibert will be here Tuesday to go forward with the Schering case.

I wanted to raise a -- briefly an issue the parties have been talking about if I may, Your Honor.

JUDGE CHAPPELL: Okay.

MR. NIELDS: We have had some preliminary discussions of scheduling, particularly in light of the Court's remarks to us on a couple of occasions. There are -- we're concerned, because there are -- when you take the Schering witnesses remaining, the Upsher witnesses and the rebuttal witnesses of complaint counsel, there are quite a few, and we have had very preliminary conversations about ways of trying to streamline that proof so that it would consume less time.

We haven't reached anything definitive yet, but we plan to have further conversations over the weekend

and then to make a report to the Court on Tuesday morning before we begin about just exactly how we think we can proceed and how long it will take, and hopefully it will be a good report, but it will be the best report we can agree on.

JUDGE CHAPPELL: Okay. Is that -- what kind of possibilities are you looking at, offering -- offering depositions instead of live or -- or is it too early to know?

MR. NIELDS: That sort of thing, Your Honor. We haven't yet agreed on a format, and maybe we won't be able to, but we are going to earnestly try to do that. We are also obviously going to look to see what witnesses we think we can drop on the grounds that their testimony may not be absolutely essential, but we're going to try to find ways of abbreviating the amount of in-court time if we can do it in a way that the parties find is comfortable.

Obviously everybody needs to be able to put into the record what is essential to their case, but we are going to work very hard to see if there are ways of doing that without consuming unnecessarily in-court time.

JUDGE CHAPPELL: Right, and just keep in mind that I don't need three or four people to tell me the

same thing. It's not like an intersection collision where everybody has the light a different color. Just keep that in mind.

MR. NIELDS: Yes, we will.

JUDGE CHAPPELL: Okay, thank you, Mr. Nields.

MR. NIELDS: Thank you, Your Honor. Oh, and I will also be able to report to the Court on Tuesday definitively whether the 25th works for me. I'm very optimistic that it will, but I still haven't been able to reach my client during the hours in which I've been in my office.

JUDGE CHAPPELL: Okay, and I have -- on the 25th, I have set another hearing at 3:30, but we can go most of the day on the 25th.

MR. NIELDS: Okay, thank you, Your Honor.

MR. CURRAN: Your Honor, at this time Upsher-Smith calls Mark Halvorsen, and my colleague Peter Carney will be handling the direct of this witness.

JUDGE CHAPPELL: Thank you.

Please raise your right hand.

Whereupon--

MARK B. HALVORSEN

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a seat.

State your fall name for the record, please.

THE WITNESS: Mark Benson Halvorsen.

JUDGE CHAPPELL: Thank you.

MR. CARNEY: Good morning, Your Honor.

JUDGE CHAPPELL: Good morning.

DIRECT EXAMINATION

BY MR. CARNEY:

Q. Mr. Halvorsen, by whom are you employed?

A. Upsher-Smith Laboratories.

Q. And what is your position at Upsher-Smith?

A. I'm the director of clinical and regulatory affairs.

Q. In that position, did you have responsibility for the clinical development of Niacor-SR?

A. Yes, I did.

Q. Could you describe, please, your post-high school education?

A. Went to the University of Minnesota, and I received my BS in chemistry in 1987, a BS in pharmacy in 1990, and my doctor of pharmacy in 1991.

Q. Did you do any internships or residencies as part of that education?

A. I did a post-doctoral fellowship at Hoffman-LaRoche in New Jersey.

Q. When did you first start working at Upsher-Smith?

A. In May of 1993.

Q. Could you list, please, the positions you've held at Upsher-Smith and the approximate dates of those positions?

A. I started at the company as clinical research and medical affairs coordinator. I was in that position for a little over a year. Then I became the clinical projects manager. I was in that position for approximately two years. Then I became the manager of clinical and regulatory affairs. I was in that position about three years. And then I came into my current position, the director of clinical and regulatory affairs.

Q. As clinical research and medical affairs coordinator and then as clinical projects manager, what were your responsibilities?

A. My primary responsibilities were to oversee the clinical trials at Upsher-Smith and specifically Niacor-SR.

Q. And then as manager and as director of clinical and regulatory affairs, what were your responsibilities?

A. Became more of oversight, where I had oversight

over the clinical and the regulatory departments.

Q. During your tenure at Upsher-Smith, have you been involved with preparing new drug applications or NDAs?

A. Yes, I have.

Q. And have you been involved with filing abbreviated new drug applications or ANDAs?

A. Yes, I have.

Q. For which drugs have you worked on ANDAs?

A. For ANDAs, I have worked on Klor Con M, pentoxifylline, Prevalite, Pacerone, Sotalol, a few more as well.

Q. And these are all Upsher-Smith products?

A. Yes, they are.

Q. Can you explain generally what Niacor-SR is?

A. Niacor-SR is a sustained release formulation of niacin, meaning it releases niacin over a period of time, a gradual release of niacin.

Q. What physical condition is niacin used to treat?

A. Hypercholesterolemia or excessive lipids basically.

Q. As part of your work at Upsher-Smith, did you have different priorities for projects that were under your aegis?

A. Yes.

Q. And when you started at Upsher-Smith, what project was your top priority?

A. Number one project was Niacor-SR.

Q. And approximately what percentage of your time was dedicated to Niacor-SR?

A. Eighty to 90 percent of my time.

Q. And do you know approximately what percentage of Upsher-Smith's clinical research budget Niacor-SR accounted for for the period of 1993 to 1998?

A. Probably about the same percentage, 80 to 90 percent.

Q. Do you know how much Upsher-Smith spent on Niacor-SR by the end of the second quarter of 1997?

A. Approximately $13 million.

Q. And do you know how that compares to what Upsher-Smith spent on other clinical research projects as of that time?

A. That was more than double all of the other projects combined.

Q. As director of clinical research, do you know why Upsher-Smith was so committed to developing Niacor-SR?

MS. BOKAT: Objection, Your Honor, leading.

JUDGE CHAPPELL: Overruled. He's not

suggesting a yes or no.

Go ahead.

THE WITNESS: Niacor-SR was a very important product to us, and we saw it as a great opportunity to expand our sales in an extremely large market of cholesterol-lowering drugs.

BY MR. CARNEY:

Q. Why did you see it as a great opportunity?

A. It really fit an unmet need. Niacin affects all of the lipid parameters. If you look at it, it lowers LDL, it lowers triglyceride, it's one of the only drugs to lower Lp(a), and it increases HDL. So, as a group, there is -- it's a unique product.

Q. Have any of Upsher-Smith's clinical trials for Niacor-SR involved treating patients with statins?

A. Yes.

Q. And how are the statins involved in those trials?

A. We had as part of our -- one of our studies, the 944 study, we had 18 weeks of combination therapy with lovastatin and Niacor-SR.

Q. And based on your experience with niacin and statins, how does niacin compare or stack up to a statin?

A. Statins focus on LDL lowering, what people call

the bad cholesterol. They're very good for that, and niacin cannot compete with their LDL lowering, but niacin increases HDL, which the statins do very little, they significantly reduce triglyceride and significantly reduce Lp(a). So, it's a give and take. You have statins are extremely good for LDL, and niacin is extremely good for other parameters.

Q. What is Lp(a)?

A. It's a molecule, it's lipoprotein A, that's very similar to LDL, which is considered the bad cholesterol, and in recent literature, it's been shown to be an independent risk factor for arthrosclerosis or coronary artery disease.

Q. During your time at Upsher-Smith, has Upsher-Smith developed or sold any other niacin products besides Niacor-SR?

A. Yes, we have.

Q. What products are those?

A. Niacor, Niacor-B3 and Slo-Niacin.

Q. Do you know when Upsher-Smith first started selling niacin products?

A. Before I arrived at the company in '93.

Q. And what is Niacor-B3?

A. That's a dietary supplement, immediate release niacin product.

Q. And what is Niacor?

A. Niacor is a prescription immediate release niacin product.

Q. And what is Slo-Niacin?

A. Slo-Niacin is a dietary supplement, sustained release niacin product.

Q. Do you know how long Upsher-Smith has been selling Slo-Niacin?

A. Again, since before I arrived at Upsher-Smith.

Q. Based on your experience with the Niacor-SR clinical trials, how does Niacor-SR compare to Niacor or immediate release niacin?

A. Could you repeat that?

Q. I'll try, yeah.

Based on your experience with the clinical trials of Niacor-SR, how does Niacor-SR compare in terms of effectiveness as compared to immediate release niacin?

A. The lipid parameters are slightly different for -- plus or minus on the five basic parameters, but essentially cholesterol lowering is the same.

Q. And if Upsher-Smith already had an immediate release niacin product, why was it looking at a slow release niacin product?

A. Well, you really want to eliminate a nuisance

adverse event called flushing. Flushing, if I can describe it, it's a warm feeling, for example, when you're embarrassed, when you feel your face flush and you get warm, a little tingling in your peripheral circulature. It's just something that people considered to be a nuisance.

Q. Is it dangerous, flushing?

A. No.

Q. In connection with its development of niacin products, has Upsher-Smith taken any special steps to develop or promote niacin products?

A. Yes. Upsher-Smith has been wonderful prior to my arrival and when I arrived at the company in allowing us to go out and work directly with international experts in cholesterol-lowering therapy. If you look across the statins and the investigators that they used, we used the same people. We were able to bring in a blue ribbon panel of experts for the Niacin Advisory Board.

Q. Now, you mentioned your involvement with the clinical testing of Niacor-SR. What was your involvement with it?

A. My involvement with Niacor-SR started from day number one, working on the individual studies, going forward, working with all of the clinical

investigators, working with the CROs. I was in charge of all of the Niacor-SR activities related to clinical.

Q. You mentioned a CRO. What's a CRO?

A. That's a contract research organization that -- it's a group that pharmaceutical companies hire to out-source work.

Q. And why are they hired for out-sourcing?

A. It's real hard to have a full staff to perform all of the activities that are in place, and it's just as easy to -- and the same cost to work with a CRO and not have the head counts internally.

Q. How many clinical tests did Upsher-Smith do for Niacor-SR?

A. We had two phase III pivotal trials and two follow-on studies.

Q. Just if you could explain what phase III is.

A. Phase III is the last phase of clinical development for gaining approval of a drug product from FDA.

Q. And on what kind of subjects is phase III testing done?

A. Phase III is on the large expanse of general patients that have the disease state you want to treat.

Q. And you said there were two pivotal clinical tests. Is there a way you refer to those tests?

A. We refer to them as -- by the study number, the placebo controlled trial was the 221 study, and the active control trial was the 115 study.

Q. And then I think you mentioned two follow-on studies. Is there a shorthand for referring to those studies?

A. Again, the numbers. The follow-on to the placebo control was the 837 study, and the follow-on to the active control trial was the 944.

Q. Could you just briefly explain what a pivotal clinical study is?

A. A pivotal study is the real basic study that FDA relies upon for approval. At this point in time, FDA required two pivotal trials to approve a drug product, so it was the primary studies that would be reviewed for approval.

Q. And does the FDA regulate those pivotal studies?

A. Absolutely.

Q. And what is a follow-on study?

A. A follow-on study is to get longer exposure to the medication that you're testing. You like to have long-term exposure to show that something doesn't occur the longer someone is on a drug.

Q. Now, for Niacor-SR, approximately how many

patients were involved in the two pivotal tests?

A. Approximately 900 patients were in the pivotal trials.

Q. And about how long did these pivotal studies take?

A. An average of 33 weeks.

Q. And that's just the patient treatment phase or in all?

A. Oh, that's just the patient treatment period.

Q. And when did the last patient finish with treatment in the pivotal studies?

A. In the pivotal studies, the last patient completed treatment in October of 1995.

Q. And about how many patients participated in the two follow-on studies?

A. Approximately 300.

Q. And do you know when the last patient completed treatment in the follow-on study?

A. The last patient completed in the follow-on studies in July of '96.

Q. Now, what's involved in the patient treatment phase of a clinical study?

A. There's a lot that's involved in the clinical treatment phase. You have your physician investigators. You have your patients. You have a

laboratory that has to run the test, such as in this case the lipid parameters. We have a dietary analysis group, because diet is very important to cholesterol lowering. We have a contract research organization that we work with to make sure all of the information collected is accurate and is on our data collection forms.

Q. About how many physicians were involved in the clinical studies?

A. We had six well-renowned physicians in the 221 study and 15 in the 115 study.

Q. And how did Upsher-Smith select or did it select the physicians for the clinical studies?

A. Oh, yes, Upsher-Smith definitely selected these physicians.

Q. And how did Upsher-Smith select them?

A. We really looked at their credentials within the lipid-lowering field and how they -- their involvement and credentials I guess are the bottom line. We went to some of the international experts in the field, and one of them is in our home town. Dr. Donald Hunninghake at the University of Minnesota is internationally known for his expertise in lipid-lowering therapy. We used Dr. Richard Pasternak from Mass General; Dr. Virgil Brown at Emery

University; and several other experts.

Q. And where were these clinical studies conducted?

A. Throughout the United States.

Q. Do you know approximately at how many locations they were conducted?

A. Each one had their own individual site, so the six centers in the 221 and 15 in the 115 study.

Q. Do you know approximately what it costs Upsher-Smith to do such clinical studies?

A. Yes.

Q. For Niacor-SR, do you have a sense of what it cost?

A. To put it in perspective, the 115 study alone, the treatment period to just treat all of the patients, was $3.3 to $3.5 million.

Q. And that's just the 115 study?

A. That is correct.

Q. What does that $3 and a half million include?

A. It covers the costs for the groups I mentioned previously, the physician investigators, the laboratory, the nutritional analysis and the contract research organization to make sure the data is collected properly.

Q. And did you have similar kinds of expenses in

the other three studies?

A. Yes, we did.

Q. Now, once the last patient had finished the follow-on study -- what did you say the date was for that?

A. The last patient completed the follow-on study in July of '96.

Q. Okay. Now, once the patients are done with that treatment, does that mean that the clinical work for an NDA is done at that time?

A. No.

Q. What remains to be done after the patients have all completed treatment?

A. There's actually a significant amount of work, it's just a different type of work. What you do is you take those data forms or case report forms, and they are put into a database. All of the data is checked to make sure it's accurate, such as you do some automatic checks. All female patients have a pregnancy test, things like that to make sure that database is clean.

Once you've got all of that entered into a computer database and cleaned, the database is locked. Then it --

Q. Okay. What -- once the database is locked, are you done at that point?

A. No.

Q. What else is necessary?

A. You continue on with statisticians, and you put together the programming for getting your results back the way you'd like to see them in data tables, and then after all of that is in place and you've audited those data tables, you write your clinical study report, which is the final activity.

Q. So that the data study reports are based on the data tables, you need the data tables first?

A. Correct.

Q. And what are those reports that you're referring to?

A. They're the final integrated reports for the individual studies.

Q. Okay. When you say "reports," there's more than one?

A. There's one report for each study.

Q. Okay. Have you heard the term "ISS"?

A. Yes.

Q. What does that refer to?

A. Integrated summary of safety.

Q. And what is that?

A. What it is is when you put an NDA together, all of your clinical -- individual clinical study reports,

you have to merge that data to get a greater picture. It's like going up a triangle. Your study reports are towards the lower end of the triangle, and as you go up, you get into more summaries and summaries, and the ISS summarizes all of the safety information from all of your clinical trials.

Q. Okay. When you say those study reports are at the bottom part of the triangle, are you talking about after the -- how does the patient phase fit into that triangle?

A. The patient phase actually comes below the individual study reports, meaning that's all of the data, all of the treatment of those patients is the lowest end and it's the raw data. That data goes into individual study reports, which then goes into the ISS, and then it goes up to your NDA.

Q. And have you heard the term "ISE" in connection with clinical studies?

A. Yes, that's the integrated summary of efficacy. It's the second half. You have safety and efficacy, and so you have a summary of each as you're going to the top of that triangle.

Q. And then is there a step after ISS and ISE as far as building your pyramid?

A. Yes, your last step is putting -- taking all of

that information and putting it into a package insert, which is really a small summary of everything you know about your drug.

Q. And in your experience in clinical work, is this post -- these post-patient activities, are they time-consuming?

A. Yes, they are.

Q. And why is that?

A. You're integrating millions of data points. You're looking at -- an individual patient may have anywhere from 50 to 75 pages of data that needs to be entered, and if you look at all the patients, you have that much for one individual patient. You put all of that up -- you have to make sure that all of that data is accurate, because the FDA will look at that information and go down and pick out individual patients and follow them through into your study reports, into your ISS and ISE. It takes a lot of time to make sure that that is all put together and accurate.

Q. Okay. So, after the last patient is done with Niacor-SR in July of '96, who's involved at Upsher-Smith with this post-patient work that you're talking about?

A. At Upsher-Smith, it was the entire clinical

research department, including myself.

Q. And did you do -- did your -- Upsher-Smith's department do all of the work on this?

A. No, we didn't have the capability to do that. We don't have the computer systems in place for that, so we were working with three different CROs. We were working with ClinTrials Research, NovaTech Sciences, a statistical group, and CSR Consultants, a group that was going to write the final study reports for us.

Q. And how do you select these CROs to work on post-patient work?

A. Well, for selecting ClinTrials, we were looking for a large firm that had experience in cholesterol-lowering trials, and ClinTrials had recently worked on the Excel trial for Merck, and it was lovastatin. It was a large study, and they had recently worked on that, and their staff was very qualified. So, we felt going with someone with experience and had worked with one of the major firms would be the best choice for us.

Q. How did you communicate or coordinate with the CROs?

A. We have weekly teleconferences to make sure everyone's on track.

Q. And was there any particular format for doing

those teleconferences?

A. Yes, we would have an agenda put out in advance of the call, and then after the call, ClinTrials would write up the meeting minutes and send them out to us.

MR. CARNEY: I want to show the witness some exhibits, Your Honor. I've taken the liberty of circulating the binders, and they're the two large binders that are on the Bench there.

BY MR. CARNEY:

Q. Sir, could you look at these two binders which are in front of you, and if you could just flip through them briefly, and for the record, they're identified as USX 1041 through USX 1145 and then USX 1146 through USX 1266.

Sir, can you identify these documents?

A. Yes, these are the agendas and meeting minutes of the weekly teleconferences with ClinTrials, NovaTech and CSR Consultants.

Q. And these were files that Upsher-Smith kept?

A. Yes. These are the clinical research department summary lists.

Q. Could I ask you to turn to what is USX 1179, it's going to be in the second binder, about a quarter to a third of the way in.

A. 117 --

Q. 1179. It bears the date June 19, 1997 on the first page. Is this the type of agenda you're referring to?

A. Yes, it is.

Q. And then at 1180, the next exhibit, if you look at the third page of that exhibit, which says June 20, 1997, and then "Minutes" at the top, are these the type of minutes you're referring to?

A. Yes, they are.

MR. CARNEY: Your Honor, I would move for the admission at this time of Exhibits USX 1041 through USX 1266.

JUDGE CHAPPELL: Do these all run consecutively?

MR. CARNEY: Yes, Your Honor, they do, and they were previously provided to complaint counsel, have been produced from the files of Upsher-Smith.

JUDGE CHAPPELL: Any objection?

MS. BOKAT: Your Honor, I have no objection to USX 1179. On USX 1180, it looks like this may not be a complete document, because the fax header at the top of the page indicates that there should be seven pages, and it looks like 3 and 4 are missing.

MR. CARNEY: It is -- it does appear from the fax header that there are those pages. This is the way

it was kept in the files of Upsher-Smith, and if we look at the Bates numbers at the bottom, they run out of order here but consecutively. I mean, there's sort of five in the same row of Bates numbers.

JUDGE CHAPPELL: So, it's your intent to offer only the pages that are included in that exhibit?

MR. CARNEY: Well, it's my intent to offer these as the -- Upsher-Smith's business record of its communications with ClinTrials and the teleconferences it had with ClinTrials.

JUDGE CHAPPELL: I'm just trying to establish if there are pages missing from the exhibit you're trying to offer. Is this the exhibit you want to offer the way it is?

MR. CARNEY: Yes, it is, Your Honor. It's the full exhibit as it existed in Upsher-Smith's files, yes.

MS. BOKAT: I'll withdraw the objection.

JUDGE CHAPPELL: Okay. So, no objection to this offer -- to USX 1041 through 1266?

MS. BOKAT: Oh, I'm sorry --

MR. CARNEY: It's the whole thing, yes.

MS. BOKAT: You were offering both binders?

MR. CARNEY: Both binders, yes, the whole sort of file from Upsher-Smith's records of the

correspondence.

JUDGE CHAPPELL: Do you want to look through those and let me know later?

MS. BOKAT: That would be useful.

JUDGE CHAPPELL: Okay. Any objection from Schering?

MR. RAOFIELD: No, Your Honor.

MS. BOKAT: Thank you, Your Honor.

MR. RAOFIELD: If I may just add what may be a helpful point, I believe that all of the documents contained in these two binders have already been admitted into evidence as a single document, SPX 1096. I believe that this is a much more useful way to have them admitted, because it will allow the parties in their briefing after trial to refer to individual ones without attaching large volumes.

JUDGE CHAPPELL: If that's true, then why don't -- why doesn't the person who offered the mega exhibit withdraw it? We don't need that much in -- we don't need a duplication in the record that is eight inches thick.

MR. RAOFIELD: Schering would be happy to withdraw that SPX, SPX 1096, upon admission of these documents, which are just broken down into the individual documents, Your Honor.

JUDGE CHAPPELL: Okay. Mr. Carney, you'll need to re-offer these exhibits after complaint counsel has a chance to look at them.

MR. CARNEY: Okay.

JUDGE CHAPPELL: So, at this time I'm not admitting them.

MR. CARNEY: We will do that, Your Honor, and I would just note that that's exactly what we've done. We've taken the exhibits, the component parts of 1096, and put them in a chronological order by sort of each document so that they are much more usable than an eight-inch file.

JUDGE CHAPPELL: All right.

Ms. Bokat?

MS. BOKAT: We'll take a look at it and get back to the Court.

JUDGE CHAPPELL: Okay, thank you.

Mr. Raofield, what was the exhibit you're withdrawing?

MR. RAOFIELD: It will be SPX 1096.

JUDGE CHAPPELL: Okay.

MR. CARNEY: Subject to admission of these documents, as I understood it.

JUDGE CHAPPELL: All right, then let's just go over this again when you re-offer these exhibits, and

then we will note for the record whether that's withdrawn or not. So, at this time we will hold off. Thank you.

MR. CARNEY: Okay, thank you, Your Honor.

BY MR. CARNEY:

Q. Dr. Halvorsen, if I could direct your attention then to the third page of that exhibit, USX 1180, and under the word "Minutes," it says, "Attendees --" I'll let you find the page, sorry. It's the third page. It's, for the record, Upsher-Smith-FTC-094047, and under "Minutes," it says, "Attendees: CTR."

Who is CTR?

A. ClinTrials Research.

Q. And do you know who these people are listed to the right of the CTR designation?

A. Yes, they were part of the Niacor-SR team from ClinTrials Research.

Q. And below that it says "USL," your name, "Marge Garske, Tiea Crane, Gina McClure."

Those are all Upsher-Smith people?

A. Correct, that's the Clinical Research Department.

Q. And those people all report to you?

A. Yes.

Q. And then it says, "CSR: Claude Drobnes."

What is CSR?

A. CSR Consultants is a group who worked with us during the actual conduct of the trials, and then they were going to put together the final reports for these studies.

Q. And then, "NT," who is that or what is that?

A. NovaTech Sciences is a statistical CRO that worked for us.

Q. And this is indicating that all of these people were involved in this phone call?

A. Yes.

Q. And then going down, there's a Roman I, Data Management/CSR Issues (By Study), and then it lists A, B -- going down to the next page, C, and on the fourth page it's got -- sorry, on the next page after that, which is 094049, it's got D, 920837.

Do you know what this refers to?

A. Those are our two pivotal and two follow-on studies.

Q. And was it your practice to discuss these in any particular format on these calls?

A. We discussed all outstanding issues or items that needed to be completed during the next week or with future dates to really make sure we were getting things done as fast as possible.

Q. And then on what is the last page of that document right below the D, there's a 2 that says, "ISS/ISE/NDA/CANDA."

What's a CANDA?

A. That's a computer-assisted NDA. The FDA is moving towards a paperless environment. So, you are now using computer applications as well.

Q. And you had a separate discussion point here then for the ISS, the ISE, the NDA and the CANDA?

A. Yes.

Q. Do you recall the time frame in which you had these conference calls with ClinTrials and the other CROs?

A. They started in May of '95 when we started working with ClinTrials and continued until 1998 when we wrapped up the project.

Q. So, they were working throughout the period of 1998?

A. Yes, they worked into 1998.

Q. Do you recall approximately when in 1998 ClinTrials and the other CROs stopped work?

A. We actually had notified them in March that we would be discontinuing the project, and then they continued on until we received all of the documentation that they had, which was just a tremendous volume of

paper, which we received in the summer of 1998.

Q. And do you recall who notified them to stop working in March of 1998?

A. I did.

Q. And why did you make the decision to notify them to stop working in March of 1998?

A. I did not make the decision myself. I notified them of the decision.

Q. Okay. And why did you notify them of the decision?

A. We had a meeting in March of 1998 in Ian Troup's office, which included Mr. Troup, Dr. Robbins and some other individuals, and when I walked out of that meeting, I was to inform the CRO that our European partner, Schering-Plough, was not going forward with the project.

Q. Okay. Earlier you mentioned something called the Niacin Advisory Board. What is that?

A. It's a panel of experts in the lipid-lowering field that we convened to really learn about our product, how they perceived it, to get their picture of niacin in the marketplace in ways that we could improve our product and improve our perception and sales of the product as we moved forward.

Q. Did you personally have any involvement with

the Niacin Advisory Board?

A. Yes, I did.

Q. What was your role?

A. I was involved in selecting the individuals to be on that panel, and I presented some preliminary information from our largest pivotal trial to them.

Q. And do you recall when you made that presentation?

A. I believe it was August of 1996.

Q. I'm going to show the witness an exhibit which is marked, it's in the binder there, the white binder, it's USX 329, if you could look at that, please and identify it, if you could.

A. What was the number?

Q. It's the first tab, it's USX 329. We've got it on the screens as well.

Do you recognize the document?

A. Yes.

Q. What is this document?

A. It's a list of the physicians that we invited to the Niacin Advisory Committee that formed up that committee.

Q. And if you turn in your binder to the third page of the document, do you know what that is?

A. That's the preliminary agenda with the list of

attendees from Upsher-Smith.

Q. And do you see the handwriting on it where it says, "Others," and then, "Bob, Jan, Denise, Tom, Scott, Don Overcast, Asta, Jim M., Mike M., Marge, Gina, Tiea," do you know who those people are?

A. Yes, they are all related to Upsher-Smith.

Q. Do they work for Upsher-Smith?

A. The majority of them, yes. I don't remember two of those names.

Q. Okay. And do you know why they worked -- why they are listed here?

A. Yes, this is primarily sales and marketing people for them to learn about niacin and the impressions of our experts, and then the Clinical Research Department as well.

Q. And then as we go down it says, "Agenda, Introduction," and then two, "Current Role of Niacin," and then below that, "Niacor-SR Clinical Data Presentation," and then your name, "Mark Halvorsen."

What does that refer to?

A. I presented some preliminary information on our largest pivotal trial at this meeting.

Q. And do you recall why you were presenting that information?

A. We really wanted to get their impressions and

see what they thought of the data, what they thought of the product in general, and how we could move forward and make this a better product.

Q. And then if you flip the page over there, it looks like a more detailed schedule, and you see it says on the left side, 9:15 a.m., "Clinical Data, 60-Minute Presentation, Protocol 920115, Study Results," and then it looks like everyone got a break, and then 10:30, "Clinical Data, 60-Minute Discussion," and below that, "EXTRA, 30 Minutes."

Do you recall what was involved in the discussion?

A. We had quite a long discussion of both the efficacy parameters and the safety parameters. What the end result was is that the panel recommended that we go forward with additional studies to help us in the marketplace and that they felt the actual efficacy data there was excellent and they felt the safety profile was fine. They were really impressed with the product.

Q. And when you say "the panel," you're referring to, if you turn to the front page where it says Niacin Advisory Committee Members, is this the panel you're referring to?

A. Yes, these are experts from throughout the United States, and Dr. Davignon was the lead

lipid-lowering physician in Canada as well.

Q. And then I'm sorry to keep flipping around like this, but if you go back to that Discussion Issues we were looking at and go one more page to what is Upsher-Smith-FTC-113067, there looks to be one, two -- five pages listing each of the doctors and then some information.

Do you know what this is?

A. Yes, it's a brief credentials of all of the experts from the various universities, from Johns Hopkins, from University of Minnesota, University of Washington, throughout the United States the experts, and Dr. Davignon from Montreal.

Q. And then on that first page of -- listing the credentials, there's something that says FATS, FATS-II, NIH, looks like an arrow and then -- I don't know, can you read the rest of that?

A. "Low HDL study." That's the recently published FATS study. Dr. Brown at that time was actually treating patients in the FATS trial, which I believe has now been published in JAMA or New England Journal.

Q. And at the bottom of the page there it says, it looks like "Pravastatin/SR Niacin (Nicotaid) Study."

Do you know what that refers to?

A. Dr. Davignon had published a study on

combination therapy on pravastatin and niacin.

MS. BOKAT: Excuse me, Your Honor, we seem to have a monitor here that's not working. We have the paper exhibits, so we can go forward with that, but maybe at a break or something.

JUDGE CHAPPELL: Okay, we can either wait or we can have someone from your office contact the computer people and have them work on it while we're in trial, if you like, as long as it doesn't interrupt the witness or Mr. Carney, your choice. Do you want to stop now or do you want to have someone --

MS. BOKAT: No, let's go forward.

BY MR. CARNEY:

Q. As a result of that discussion and this panel, did Upsher-Smith take any specific steps regarding niacin?

A. Well, Upsher-Smith -- we put together -- my department put together two protocols that would expand on the Niacor-SR treatment, but we didn't want those protocols to get in the way of completing the final study reports and filing with the FDA. That took priority.

Q. And if you'd turn to the next tab in your exhibit binder there, which is CX 0714, do you recognize this document?

A. Yes.
Q. What is it?
JUDGE CHAPPELL: Excuse me, is everyone else's monitor working?
MR. NIELDS: Ours is, Your Honor.
MR. CURRAN: Ours is, Your Honor.
JUDGE CHAPPELL: Susanne?
THE REPORTER: Yes.
JUDGE CHAPPELL: You may proceed.
BY MR. CARNEY:
Q. Do you recognize this document?
A. Yes, I do.
Q. What is it?
A. This is a protocol synopsis from one of the protocols that the advisory panel recommended we perform.
Q. And if you look down to where it says, "Objective: To compare the efficacy of Niacor-SR and fluvastatin alone and in combination," what does this refer to?
A. It's a combination therapy trial with a statin.
Q. And why was that of interest?
A. Well, the statins are the primary LDL-lowering drug on the marketplace, and if you look at statins alone, the large percentage of patients do not reach a

treatment goal, which is NCEP, National Cholesterol Education Panel, goals, NCEP, and the way to reach those goals is really to go after combination therapy, and with niacin you hit the parameters that the statins don't, so you get an overall much better cholesterol panel.

Q. Did you -- did Upsher-Smith need to do this study to get approval for Niacor-SR?

A. No.

Q. On the second page where it says, "Study Procedures," it says in the third line down, "The dosing schedules are as follows," and then it lists under 1 several things, and one of them is "1500 mg QHS for 18 weeks."

What does that mean?

A. It means the patients would be taking 1500 milligrams of Niacor-SR at bedtime for 18 weeks. The QHS is a Latin abbreviation which means at nighttime or at bedtime dosing.

Q. Was there any significance to this dosing schedule?

A. Yes, we had -- our previous studies had performed BID dosing.

Q. What's BID?

A. Which means twice a day, and this would be

once-a-day dosing at bedtime.

Q. And why were you proposing to look at bedtime dosing?

A. Well, your largest cholesterol production in the body occurs overnight, typically from 2:00 to 5:00 or 2:00 to 6:00 a.m., and that to deliver the drug and have the most drug in the body at the time that you have the largest synthesis of cholesterol would be the best way to treat it, but it would also help with the nuisance adverse event of flushing. If you're sleeping and you have flushing, you typically won't feel it. So, that's another improvement.

Q. Okay. And if you turn to the next document, which is CX 1043, do you recognize this document?

A. Yes, I do.

Q. What is this?

A. This is the second protocol that the advisory panel recommended.

Q. Do you know who drafted this?

A. Most likely myself or someone in my staff and I reviewed it.

Q. Okay. And the -- where it says, "Objective," on the left-hand side of the page, across from that it says, "To compare the safety and efficacy of three different dosing schedules."

What does that refer to?

A. I think you need to look at the next page as well in that it's three different dosing schedules of Niacor-SR.

Q. And this is next to where it says, "Study Procedures," and then 1, 2, 3?

A. Correct.

Q. And what were you comparing?

A. We were looking at the dosing that was used in our previous trials, the QAM, QPM, versus at-bedtime dosing.

Q. And the at-bedtime is the QHS?

A. Correct.

Q. If you'd turn to the next page, at the bottom of the page -- and this is SP 1600115 -- there's a sentence that starts there, "There may be some benefits in once-a-day bedtime dosing since this correlates with cholesterol production in the liver."

Is that what you were referring to earlier?

A. Yes.

Q. Okay. And then if you'd turn the page again, on the -- under where it says, "3.2, Dosing Regimen," the last sentence says, "Dosing will be twice daily with meals or a single dose with the evening meal, depending on randomization."

What did this mean?

A. Actually, that sentence is partially incorrect.

Q. Which part is incorrect?

A. The second half. The first dosing would be dosing arm will be twice daily with meals, that's dosing regimen one, which is what we performed in our previous trials, and then dosing regimens two and three would be a single daily dose at bedtime instead of the evening meal.

Q. Now, you mentioned flushing as a nuisance adverse event. Was flushing a problem for Niacor-SR?

A. Not a problem, no.

Q. Do you know how it compared to the flushing in immediate release niacin?

A. Our pivotal trial, the 115 study, looked at that and showed that Niacor-SR significantly reduced the number of occurrences of flushing at least fourfold.

Q. And when you say number of instances of flushing, what do you mean by that?

A. The total number of times someone flushes. If you flush once out of every -- once a month, that's no big deal. If you're flushing multiple times a month and maybe even on a daily basis, that gets to be a real nuisance.

Q. Just back to those protocols for a second, you mentioned Upsher-Smith did not conduct those in 1996 or 1997, actually perform the studies?

A. No, we did not.

Q. And why was that?

A. It was really because we put filing the NDA as a much larger priority for us. When you're getting into a market such as that, introduction to the market is the best -- I mean is the most important thing, and Upsher-Smith had put a high priority on getting that NDA complete and filed.

Q. And you couldn't do -- you couldn't do that simultaneously, the studies and get the NDA approved?

A. We just didn't have the staff or the resources to do all of that at one time.

Q. Sir, do you know what a pharmacokinetic or PK study is?

A. Yes, I do.

Q. What is that?

A. A pharmacokinetic study is that you -- someone takes a dose of medication, and then you take serial blood draws over time, approximately once an hour, every two hours, and then you plot the concentration of drug in the plasma or blood over time, and you look at how -- it forms a curve as to how the body's exposed to

medication.

Q. And what's it really looking to study in layman's terms, if you could?

A. Absorption and elimination of the drug, how you absorb it from the dosage form and how you eliminate it.

Q. And is a PK study different from the clinical studies that you've been describing earlier, the pivotal studies and the follow-on studies?

A. Yes, they are.

Q. How is it different?

A. Well, it's much shorter, cheaper, and just easier to complete.

Q. Is a PK study required for FDA approval of an NDA?

A. Yes, it is.

Q. And is it required for an ANDA?

A. Yes, it's just a different type. In an ANDA, you're comparing an innovator and a generic drug, whereas for an NDA, you're typically just examining your own drug.

Q. So, for either an NDA or an ANDA, one has to do PK work?

A. Yes.

Q. In terms of working time, how does the PK study

compare to the work that's involved in doing the clinical studies that are required by the FDA for an NDA?

A. They're just much smaller in number of patients significantly, because they're not patients, they're subjects; much smaller in length of time, shorter; and cost, their greatly reduced cost compared to a clinical safety and efficacy study.

Q. Did Upsher do any PK studies for Niacor-SR?

A. Yes, we did.

Q. What PK studies did you do?

A. We performed a single-dose study, meaning the patients took one dose of medication and had blood draws taken, and we performed a multi-dose study where they had several doses of medication taken and then serial blood draws taken.

Q. And why did you do a multi-dose study?

A. We really did it to show the FDA -- we were in discussions with the FDA. At one time we were told we did not have to perform a multi-dose study, and then at a subsequent meeting we were told yes, we did have to do that, and we wanted to show the FDA that with niacin, you don't get blood levels from a typical drug. You see the effect, the lipid lowering, but blood levels have nothing to do with the pharmacodynamic

effect. You just -- blood levels are really not important for the action of the drug itself.

Q. Okay. And after you showed these results of the multi-dose test to the FDA, what happened next?

A. They agreed that we did not have to do a multi-dose plasma study. They agreed that we would only need a single-dose urine study for FDA approval.

Q. And do you recall when they agreed to the single-dose urine test?

A. It was during a meeting in February or March of 1997.

Q. Okay, if you could turn in your binder of exhibits there for a moment to what is the next tab, and that is CX 0917. Could you identify that document for me, please?

A. It is the -- a submission from myself and Upsher-Smith to the FDA regarding a meeting that was held on February 7th, 1997 to discuss the PK issues.

Q. Okay. If I draw your attention to the bottom paragraph there, and it says, "Also enclosed for your review is a proposed protocol for the single dose, 3-way crossover, pharmacokinetic evaluation of niacin and its metabolites in urine (see Attachment 2), as agreed to during the February 5, 1997 meeting."

Is this what you were referring to before as

far as them agreeing to a single-dose test?

A. Yes, they agreed to the design, and we drafted a protocol for their review.

Q. Okay. And then if we leaf through this document to what at the bottom is labeled as 107439, it's right behind a page that says Attachment 2, do you know what that -- I guess what the following pages are? And it runs -- it appears to run to Attachment 3, which starts on 107450.

A. Yes, this is our draft protocol that we sent to the FDA for their review.

Q. Okay. Now, I'm going to ask you to turn to the next exhibit, which is USX 0281. Do you know what this document is?

A. Yes, it's a response from the FDA to Cindy Farner in our regulatory group regarding the draft protocol that we submitted to FDA.

Q. And what was the significance or importance of this fax, if any?

A. It basically is their final agreement to the protocol, just asking us to add a fourth arm to the protocol, and the single-dose urine study was ready to go.

Q. So, this is a -- this is the fax approving a single-dose study?

A. Yes, it is.

Q. And you received this in March of '97?

A. Correct.

Q. And then if you go to the next exhibit in the binder, which is SPX 0331, do you recognize this document?

A. Yes.

Q. And what is this document?

A. This is the final protocol incorporating the FDA's comments.

Q. And this was the -- and what were you -- who prepared this protocol?

A. Myself or someone in my group with my review.

Q. And what was the purpose of this protocol?

A. The purpose of this protocol was to be prepared to immediately start a -- the PK study.

Q. And do you recall when this document was prepared, this study was prepared?

A. I don't recall, but I can see in the upper right-hand corner that it's dated June 4th, 1997.

Q. Okay. That's on the third page, the 111279?

A. Correct.

MR. CARNEY: Your Honor, at this time we would move for the admission of SPX 331 into evidence.

JUDGE CHAPPELL: Any objection?

MS. BOKAT: No, Your Honor.

MS. SHORES: No objection, Your Honor.

JUDGE CHAPPELL: SPX 331 is admitted.

(SPX Exhibit Number 331 was admitted into evidence.)

MR. CARNEY: Thank you, Your Honor.

BY MR. CARNEY:

Q. What was the next step with regard to the PK study once you had prepared this protocol?

A. Well, what we did is we actually needed to get a bioanalytical method, a method that would measure the drug in urine, and so we started two activities. We had two contract research laboratories working on a method competing with each other to develop that method. We wanted to get this done as fast as possible. So, we had MDS Harris and Cedra Laboratories competing with each other. We were paying double the cost, but we wanted to get this method in place as soon as possible.

Q. Have you ever put two CROs in competition like that before?

A. No, we haven't.

Q. Have you ever done that since?

A. No.

Q. What was the next step after that?

A. The next step, which was actually at the same time, is that we took this protocol, and we actually used it for a pilot study with Slo-Niacin, our dietary supplement sustained release niacin, so that we could have some samples, urine samples, and use them in developing the method to measure the drug in urine.

Q. And how did you go about developing a method to measure the level in urine?

A. Well, they needed to go forward and first see if they could detect the drug in urine, and then subsequently, you need to have some samples to see how low you need to go. For example, with niacin, it's -- very little is available in plasma. So, in moving to urine, we weren't sure how low you had to measure to find any of the drug in the urine.

Q. And who was doing this work that you're referring to?

A. The analytical was the MDS Harris and Cedra Laboratories.

Q. And did they ever develop a final methods validation?

A. Yes, they did.

Q. And do you know when they were working on -- in what period they were working on the methods validation?

A. They started fairly quickly after we resolved the protocol issues with the FDA, and they continued into 1998.

Q. And do you believe MDS Harris was diligent in conducting that work in '97 and '98?

A. Absolutely.

Q. Do you think you could have done it faster if you had done it in-house at Upsher-Smith?

A. We did not have the capabilities to run biological samples inside Upsher-Smith, but from a selection standpoint, all of the major pharmaceutical firms, generic firms, worked with MDS Harris and Cedra. They were two of the top labs in the country.

Q. And do you know approximately how much Upsher-Smith spent on developing this final method valuation -- validation that you were talking of?

A. Approximately $400,000.

Q. And is that the only money Upsher-Smith was spending on developing Niacor-SR in that period?

A. No.

Q. What else was it spending money on for Niacor-SR in that period?

A. We were working with our CROs from the clinical standpoint, completing the final study reports, the ISS and the ISE. We had multiple CROs, as I mentioned

earlier, working on that project as well.

Q. In the fall of '97 or in the spring of '98 when MDS Harris was working on this method validation, did you ever call up Schering-Plough and ask them for help on this?

A. No.

Q. Why not?

A. We didn't need to. PK studies are easy, and we had some of the top labs in the country working on this, labs that all of the firms are familiar with. If you were to ask any of the major pharmaceutical firms, they'd say go to some of the experts in that area, and MDS and Cedra were experts in that area.

Q. Do you have a sense of how many people were working on this PK study work in the fall of '97 at MDS Harris?

A. Multiple individuals. I don't know the exact number, but they are a very large laboratory, and they are very skilled in their work.

Q. Are you familiar with a product called Niaspan?

A. Yes, I am.

Q. What is Niaspan?

A. Niaspan is a sustained release niacin product marketed by Kos Pharmaceuticals.

Q. Do you follow stock prices?

A. Yes, I do.
Q. How do you follow stock prices?
A. I use my Yahoo web page that has them all listed.
Q. And that Yahoo web page, is that on your computer?
A. Yes, it is.
Q. And where is that computer?
A. It's on my desktop computer in my office.
Q. And how do you follow it with the Yahoo page?
A. I list the various companies that I want to follow to watch stock prices and any press releases on them from a competitive standpoint.
Q. And did you follow Kos' stock price?
A. Yes, I did.
Q. And did you follow it in 1997?
A. Oh, yes. I watched it from their initial IPO.
Q. Do you know what Kos' stock symbol is?
A. KOSP.
Q. And why did you follow Kos?
A. They were our major competitor. They had a sustained release niacin product, we had a sustained release niacin product. I really wanted to be able to find as much information as possible about their product and the company.

Q. Did you get any more information besides their stock price there?

A. Yes, I did. That's where I picked up their press releases.

Q. Do you know what their stock price was in June of '97?

A. In the thirties.

Q. Do you know if Niaspan ever got FDA approval?

A. Yes, it did.

Q. Do you know when it got approval?

A. In July of 1997.

Q. And before it got approval, what type of information did you have about Kos' Niaspan product?

A. There was limited information available. We had the IPO documents that they had publicly made available, and there were one or two abstracts from the American Heart Association meeting or the American College of Cardiology meeting, I don't remember which.

Q. And what kind of information were you looking for in that Kos material?

A. I was looking for both safety and efficacy information.

Q. And based on what you saw in June of 1997, how did Niaspan stack up to Niacor-SR?

A. I felt they were virtually the same.

Q. And is that in terms of efficacy?
A. Efficacy and safety.
Q. Were you aware at any time of a cross-license agreement between Kos and Upsher-Smith?
A. Yes, I was.
Q. And what was your understanding about that license agreement?
A. I knew they needed to license our patents to make sure they could have their IPO.
Q. And do you know roughly when that occurred, the cross-license I mean?
A. Sometime in early '97.
Q. And did you ever -- did you ever see the terms of the cross-license?
A. No, I did not.
Q. Did it have any significance to you?
A. No from a financial standpoint, but it really told me that if they had to license patents from us, our formulations had to be very similar and our products had to be very similar.
Q. And were you aware of this cross-license agreement in June of 1997?
A. Yes, I was.
Q. And regarding your opinions on how Niacor and Niaspan stacked up, prior to June of 1997, did you ever

discuss that with anyone at Upsher-Smith?

A. Oh, yes.

Q. You sound sure of that. Why are you sure of that?

A. Well, they were our main competitor. We would take any information that we could get on them and discuss it internally as to how they compared versus our product.

Q. And is that just people in the market -- in the -- I'm sorry, in the clinical department that were reporting to you that you discussed it with?

A. No, that's throughout the entire company.

Q. Okay. You said Kos was approved in July of '97?

A. Yes.

Q. After Kos' Niaspan received approval, was there more information or less information or how did the information on Kos compare?

A. A lot more information became available, because now they were talking about what was actually included in their NDA. Information that's submitted in an NDA is confidential unless it's released by the company who submits the information or upon approval you learn more about the product.

Q. What kind of information was available in what

you were seeing about the NDA?

A. It listed their indications, what FDA had granted for them to promote, and it listed efficacy information, and it included safety information.

Q. Did anything that you saw in the information that was available post-approval on Kos' Niaspan product affect your opinion or your notion of how Niaspan and Niacor compared?

A. No, not at all.

Q. Do you recall what indications Niaspan received after it was approved?

A. Yes.

Q. And what were those indications?

A. They received a general indication for lowering LDL. They received a general indication for lowering triglycerides. They received an indication for reduction of nonfatal myocardial infarction, received an indication for the halting progression or regression of arthrosclerosis, which is basically coronary artery disease, the clogging of the artery.

Q. Did any of those indications surprise you?

A. Yes.

Q. Which indication surprised you?

A. The last two, the reduction in nonfatal myocardial infarctions and the halting progression or

regression of arthrosclerosis.

Q. Why was that a surprise to you?

A. Because I was not aware that they were performing outcome studies.

Q. Why would outcome studies have been significant?

A. Outcome studies were really things that companies performed subsequent to approval. It was really big in the marketplace at that time. All of the statins were coming out with studies that showed outcome. It's the true effect of the drug on someone.

When you lower cholesterol, that's great, but that's a number. An outcome study is you're looking at do you increase that person's life, do you reduce the medical result of the increased cholesterol. So, it's really proof that lowering that number has a long-term improvement effect on a patient's health.

Q. At that time, in June or July of '97, did you expect Niacor-SR to get those similar indications for the arthrosclerosis and the myocardial infarctions?

A. No, I did not.

Q. And why was that?

A. Because we had not performed outcome studies. We had not performed studies that looked at the long-term effect of lowering cholesterol with

Niacor-SR.

Q. And did the fact that you didn't think you were going to get those indications have any effect on your opinion about Niaspan and Niacor and how they compared?

A. Oh, no, not at all.

Q. You still thought they were similar in efficacy?

A. Yes.

Q. And as to safety as well?

A. Yes.

Q. What is the significance for a product to have those two indications that you mentioned?

A. It allows a company to go out -- FDA has approved that, so you can go out and promote that to physicians, you can promote it in direct-to-consumer advertisements, you can show, look, if you take our medication, we can reduce your incidence of heart attack via myocardial infarction, we can promote the halting or regression of arthrosclerosis. So, it's really a benefit for a company to be able to say that.

Q. So, it was a benefit or an advantage for Kos then?

A. Absolutely.

Q. Okay, I'd like to, if you would, please, to turn to the next exhibit, which is CX 1090, and if you

could identify this for me once you have had a chance to look at it.

A. This is a memo written by our director of marketing.

Q. And that's Bob Coleman?

A. Correct.

Q. And do you see handwriting on the document?

A. Yes, I do.

Q. Do you know whose handwriting that is?

A. That's my writing.

Q. And do you remember why you were writing on this document?

A. Yes, because there were several things I disagreed with or were in error.

Q. And do you recall in particular what those were?

A. Well, some of it was the indications. In fact, the two that we've been talking about, the reduction in nonfatal myocardial infarction, the slowing progression and promoting regression, the fact that they didn't get the proper indication for the general lipid-lowering parameters correct.

Q. And then at the bottom do you see where it says, "It appears that Niacor-SR will have a similar clinical profile versus Niaspan as it relates to the

reduction of LDL. However, Niaspan has a decided advantage on the reduction of triglycerides and the increase of HDL," did you agree with that sentence?

A. They may have individual parameter advantages or disadvantages, but when you look at the five as a whole, they're equivalent.

Q. Okay. And does that relate to the next sentence, which it appears you've marked up, when you're talking about all five of the parameters?

A. Yeah, lipoprotein A, Lp(a), Niacor had a significantly better profile than Niaspan.

Q. Then if you flip the page, it says, "Observations: The Niacor-SR currently in development will be a late entry into the Lipid Management Category. Based on the information at hand it," and then you've handwritten in there, "The Niacor-SR product will not have the same indications as the Niaspan product," and then the next sentence is, "Approval of the present form of Niacor-SR is not eminent and may face delays."

What was that discussing?

A. It really was discussing what indications were there, and we would not have the same indications as a Niaspan product, but in my mind then and today is that these products will be identical.

Q. And then the next section says, "Possible Alternatives."

What's this discussing?

A. Alternatives, we looked at -- once Kos received approval, we looked at three options. One was to go forward with our NDA as planned with no additional studies and what the cost of that would be. We looked at modifying our NDA and immediately performing the two studies that our advisory board had recommended and what the costs involved with that would be. And then we looked at a third option of preparing an ANDA to the Kos product.

Q. And do you recall which option Upsher-Smith followed?

A. At this point in time, we actually had a parallel path of an NDA and an exploratory ANDA project.

Q. What do you mean by "parallel path"?

A. In that we had two teams in place. We had a team of individuals working on a generic to the Kos product, and we had a team of individuals working on the NDA.

Q. And for how long did that parallel path continue?

A. For approximately two or three months.

Q. So, for two or three months, you had two teams working on two alternatives?

A. Yes.

Q. And do you know when approximately those parallel paths ended or something changed?

A. In the November time frame, Kos released some sales information, and they were a lot lower than expected.

Q. And what was the significance of that?

A. It really showed that for us to go forward with a generic product -- you need to have a certain level of sales to make that successful, and it appeared that they might not reach that level, and so we discontinued our ANDA project.

Q. And when did you discontinue the ANDA project?

A. That was at the end of '97. I don't remember exactly when.

Q. Okay. I just want to call your attention to where it says, "Possible Alternatives" in Exhibit 1090. You've got handwritten there with an arrow pointing at the paragraph, "Actually, the current NDA would be cheaper. The revised NDA to match Kos would be more expensive."

What is that referring to?

A. It refers to the two NDA options that I

mentioned earlier. If we were to go forward with the current NDA as planned, we would spend approximately $1 to $2 million, and if we went forward with the NDA and included the two more studies to get this outcome information, we would be spending significantly more dollars. Those studies alone would cost $3 to $4 million, and then we would have to put the NDA together after that.

Q. Sitting here today, do you believe that your statement that the actual -- actually the current NDA would be cheaper was correct?

A. Oh, yes.

Q. Okay. And have you learned anything since this time regarding how Kos got its indications for arthrosclerotic -- arthrosclerosis and myocardial infarctions?

A. Yeah, I subsequently learned after their approval, when the FDA released public documents, which takes -- it was about a year later after approval or longer, they released public information, and when I read that public information, I found that the FDA had actually granted the myocardial infarction and the arthrosclerosis indications to Kos without Kos asking for them. They actually added it to their package insert, and Kos didn't supply data for it. They took

it from the literature and said we suggest adding these indications.

Q. So, Kos didn't have to do the kind of studies that you were describing here to get those indications?

A. No, they did not.

Q. And you -- but you didn't know that at the time?

A. No idea.

Q. Based on what you know now about Kos' product and your product, Upsher-Smith's product, do you believe that Niacor would have received those same indications?

A. Oh, yes --

MS. BOKAT: Objection, speculation.

MR. CARNEY: Your Honor, he's testified that he subsequently received information regarding the two products and how they -- how the designations were given to Kos.

JUDGE CHAPPELL: He's a fact witness, isn't he? Isn't he a fact witness?

MR. CARNEY: Yes, he is a fact witness, Your Honor.

JUDGE CHAPPELL: Sustained.

MR. CARNEY: Thank you, Your Honor.

BY MR. CARNEY:

Q. Have you seen the package insert for Kos' product?

A. Yes, I have.

Q. And did you at any time prepare a package insert or a draft package insert for Upsher-Smith's Niacor-SR product?

A. Yes, I did.

Q. And in a package insert -- well, what does that contain, a package insert?

A. A package insert contains all of the information about your product. As I mentioned, it's the pinnacle of the triangle of the information that you've generated regarding your product, but it also includes information from the literature. You can't perform all the studies with your product, so they allow you to put in articles from other investigations in your package insert.

Q. And did you review the literature that's referred to in Kos' package insert?

A. Yes, I did.

Q. And how did it compare to the literature referred to in Upsher-Smith's package insert?

A. We contained all of the same study information in our package insert from other investigators. In fact, ours had -- draft package insert had more

information regarding studies with niacin.

Q. And which studies did the two package inserts have in common?

A. They had the ones by Dr. Greg Brown, the FATS study; they have a study from Dr. Blankenhorn, I believe that's the class study; and they include the Coronary Drug Project, which really is the original study of niacin, and in that study they showed a reduction in myocardial infarctions and a reduction in -- or I mean an increase in long-term survival.

Q. Do you recall any significant differences between Upsher-Smith's draft package insert and Kos' package insert for Niaspan?

A. No.

Q. If you could turn to the next exhibit, please, which is USX 342, and take a minute and if you could identify that for me when you have found it.

A. These are meeting minutes from an ER niacin meeting, which was our generic project to Kos' product.

Q. And it's got listed there attendees. Did you attend this meeting?

A. Yes, I did.

Q. And do you recall what the purpose of the meeting was?

A. The purpose was to discuss the overall project

and to select specific strengths to move forward with.

Q. And do you know if in November of -- well, let me back up.

When it says ER niacin, do you know what that refers to?

A. That is the ANDA project.

Q. As -- as distinct from the NDA project?

A. Correct.

Q. And do you know what the status of the NDA project was at the time of this meeting, November 7th, '97?

A. It was going forward.

Q. When you say the NDA was going forward, what do you mean by that?

A. It was an active project that was taking a lot of resources.

Q. Okay. And then what is being discussed in this ER niacin meeting which you said relates to the ANDA?

A. In reviewing the ANDA project, Kos came up with -- let's see, I believe it's four strengths, 375 milligram, 500 milligram, 750 and 1000 milligrams, and at that point in time, FDA required three bioequivalent studies for each strength, and we wanted to be able to get a strength out there as soon as possible, so we were trying to select which strength would be most

commonly used.

Q. And were you still monitoring what Kos' stock price was at this time?

A. Oh, yes.

Q. And were you still keeping track of information from Kos?

A. Yes, that was my best way to pick up press releases on the company.

Q. In the -- after the attendees paragraph, in the second -- well, two paragraphs down, the second sentence there, it starts, "The initial Niaspan marketing approach is viewed as unrealistic, attempting to pursue first line therapy status against the statins for close to the same cost."

Do you know what this was referring to?

A. Yes, I do.

Q. And what was it referring to?

A. Kos marketed their product as a first-line therapy for lowering LDL, and that's not its role in the cholesterol market. The role is as an adjunct to statins and as combination therapy.

Q. And then if you skip down a little bit there to where it starts, "The general perception is that Niaspan will likely be forced to modify its marketing strategy in the near future, which may affect the

principal tablet strength prescribed."

What's that referring to?

A. Well, we felt that with their first-line therapy market introduction that that just wasn't going over well, and as we could tell, they were having difficulties trying to promote this product in direct competition with statins, and so we didn't know which strength would become most popular when they might have to change their strategy and marketing.

Q. But your decision as to the tablet strength was based on what Kos was doing?

A. Yes.

Q. If you go down to the bottom of the page, it says, "It was determined that Marketing will continue to accrue Niaspan data and provide monthly updates. Upsher-Smith representatives attending the American Heart Association conference will look for Niaspan presence and summarize the available information."

What's that referring to?

A. It meant that we were going to have continuous monitoring of what Kos was doing with their Niaspan product.

Q. Now, this meeting is in -- appears to be on November 7th, 1997. Do you know what happened to Kos subsequently?

A. Sometime in November they released their sales results, and they were not very strong.

Q. And did that have any significance to Upsher-Smith's decisions on its ANDA for niacin -- Niacor-SR?

A. Yes, it did.

Q. Do you know when the ANDA was put on hold?

A. Fairly quickly after that information was received. They weren't meeting sales expectations, and it meant a decreased opportunity for Upsher-Smith.

Q. Couldn't Upsher-Smith have continued with its product even though Kos' product hadn't done well at that time?

A. We could have, but you typically look at what type of market the innovator has as to whether you'd want to introduce a generic.

Q. And would it have been any different if you were talking about an NDA rather than the ANDA, which is based on an innovator?

A. Yes, it would make some difference, but if someone enters the market with a similar product and they fail to get a large following, how are you going to come out with a very similar product right after that and generate improved sales if you don't have anything that's unique?

MR. CARNEY: Your Honor, I'm at a natural breaking point if you wanted to stop for a break, or I can continue as the Court pleases.

JUDGE CHAPPELL: Let's go until past 11:15.

MR. CARNEY: Good enough, Your Honor.

BY MR. CARNEY:

Q. Dr. Halvorsen, were you involved with any presentations to other companies by Upsher-Smith regarding licensing Niacor-SR?

A. Yes, I was.

Q. And do you recall what companies those were?

A. We presented to Searle in Chicago and four European companies.

Q. What kind of company is Searle?

A. Searle's a multinational pharmaceutical firm.

Q. And do you recall when that Searle presentation was?

A. It was the end of May 1997.

Q. And do you recall what the purpose of the presentation was?

A. The purpose was to present Niacor-SR to them and determine their interest in licensing Niacor-SR.

Q. Do you recall who attended on behalf of Upsher-Smith?

A. Yes, I do.

Q. Who was that?

A. It was myself, Vickie O'Neill, Lori Freese and Dr. Greg Brown and Dr. Claude Drobnes.

Q. Do you recall what the format of the presentation was?

A. The format was to present the cholesterol market, present the role of niacin in the cholesterol-lowering market, and then for myself to present the preliminary results of the two pivotal studies, the 115 and 221.

Q. Can I ask you to turn to what's the next exhibit in the binder? It's USX 538.

Could you identify that document for me, please, when you have a chance to look at it?

A. It's -- the first page is the end of a three-ring binder.

Q. You mean the -- by "end," do you mean spine?

A. Yes. And the contents appear to be my presentation -- overhead presentation slides and with an agenda for the Searle meeting.

Q. And was all of this exhibit, all of these pages, presented to Searle?

A. Most likely not. The majority of it was, but I always carried a couple backup slides with detailed information where I think they might ask a question.

Q. Did they receive -- was it done by overhead as well as hard copy presentation?

A. Well, these appear to be the majority of my personal overhead slides with -- the front appears to be similar to a handout, to what they were given. They were given a hard copy, a small reduced, of the slides that were presented at the meeting.

Q. And as I'm looking at the second page of this document, it says under what is Roman V, "Niacor-SR, Clinical Studies, Dr. Mark Halvorsen."

What was it that you discussed regarding clinical studies?

A. I presented the efficacy information at this meeting.

Q. And then do you see where also it says below that, "Safety, Dr. Claude Drobnes"?

What -- do you recall what she discussed?

A. Dr. Drobnes presented the safety information. She and I acted as safety monitors during the treatment phase of the study, so she was familiar with the safety information.

Q. Did she have any other role with regard to Niacor-SR clinical studies?

A. Yes, besides the treatment phase, her group also was the group completing the final study reports

for the Niacor-SR individual studies, and then preparing the ISS and ISE.

Q. And then under VI it says, "Niacin-Practical Applications, Dr. Greg Brown."

What was Dr. Greg Brown's role?

A. Dr. Brown was -- his role was to present niacin in a practical sense, meaning how does he use niacin in his practice, what does he see as the advantages of niacin, and really to bring his -- a world-renowned physician into -- with Upsher-Smith in representing us.

Q. And how was -- how was Upsher -- how did Upsher-Smith come to have Greg Brown join them for this trip?

A. We had been working with Dr. Brown, supplying him with niacin for his various studies that he was performing. We primarily provided him with our Slo-Niacin product and with immediate release niacin.

Q. Do you recall whether Searle expressed interest in Niacor-SR to you?

MS. BOKAT: Objection, hearsay.

JUDGE CHAPPELL: What are you offering it for?

MR. CARNEY: I'm offering it for what Upsher -- Upsher-Smith's understanding of Searle's interest was, not what their actual interest was.

JUDGE CHAPPELL: Are you offering it for the

truth of the matter asserted?

MR. CARNEY: No, I'm not, Your Honor, just for what Upsher-Smith understood.

MS. BOKAT: I don't know that what Upsher-Smith understood is relevant.

MR. CARNEY: Your Honor, part of complaint counsel's allegations is that Niacor-SR is somehow not a legitimate drug or not worth the value -- worth significant value. Whether or not -- and they have also raised a contention as to whether or not anyone was bidding or interested in the product. What Upsher-Smith understood about the interest in the product is highly relevant.

JUDGE CHAPPELL: Well, we're not to relevance yet. Nobody's saying it's not relevant. And the question was does he recall if they expressed interest. It calls for his state of mind, so therefore I'm going to overrule the objection. You may answer.

Susanne, would you read the question back.

(The record was read as follows:)

"QUESTION: Do you recall whether Searle expressed interest in Niacor-SR to you?"

THE WITNESS: Yes, they did.

BY MR. CARNEY:

Q. And what was that expression?

A. They were interested in the product, but they had a higher priority item that they wanted to take care of immediately. They were launching a large product, so they were definitely interested, they just needed a little more time so that they could launch this other product first.

Q. And do you know how much time they needed?

A. No, I don't.

Q. Did you have any follow-up with Searle personally?

A. No, I did not.

Q. Why not?

A. That was the role of Vickie O'Neill, who's here on the agenda. She was in charge of business development, and follow-up was to be taken care of by her.

Q. Now, you mentioned you were involved in presentations to other companies. Which companies were those?

A. There were four companies in Europe, two in Paris and two in Barcelona, Spain.

Q. And do you know what the purpose of -- what was the purpose of those presentations?

A. The purpose was to determine their interest in licensing Niacor-SR for Europe.

Q. Did you have an understanding at that time as to what kind of European partner Upsher-Smith was looking for?

A. We did not have the expertise in marketing a product in Europe or getting a product approved in Europe, so we were looking for a company that would be able to understand the regulations in Europe and to market the product across Europe in multiple countries.

Q. And what was the format of the presentation used in Europe?

A. Similar to the Searle presentation in that we would introduce the lipid-lowering market, introduce the role of niacin in that market, and then I would go over the preliminary results from the pivotal studies.

Q. What sort of media did you use to make the presentation?

A. Overhead presentations.

Q. And were there hard copies as well?

A. Hard copies were distributed to the attendees, and I had my own hard copy with slides.

Q. Can you turn, please, to what is CX 1023? Can you identify that for me, please?

A. This appears to be my hard copy of the presentation.

Q. This looks pretty similar to the last document.

How do you know this is from the European -- from that presentation?

A. Well, if you look through and get up to -- let's see, it's page 094141, and if you look at the introduction slides, they were tailored to what was going on in Europe, using the European Society of Cardiology, the British Heart Foundation. That implies that we were using -- we were presenting this to Europe.

And then if you go to the last page of the document, 094199, I actually wrote down the name of the perfume my wife wanted me to buy in Paris.

Q. Okay. What was your role in that presentation?

A. I was to present the clinical safety and efficacy information.

Q. And what was Ms. O'Neill's role in the presentation?

A. She was there to represent business development and to serve as the future contact with these companies.

Q. And you made a presentation at each one of these companies separately?

A. Yes, we did.

Q. Was anyone else present from Upsher-Smith for these presentations?

A. It was myself and Ms. O'Neill, and then in Paris, a gentleman, David Pettit, joined us.

Q. Who is David Pettit?

A. He represents a business development firm in Europe.

Q. And why was he there?

A. He was serving as a consultant for Upsher-Smith.

Q. Had he helped you arrange these meetings?

A. Yes, he had.

Q. Do you recall when you returned from the European trip?

A. Yes.

Q. When was that?

A. That was in early June 1997.

Q. And had the -- any of the European companies expressed interest in Niacor-SR?

A. Yes, they had.

Q. Do you recall the level of interest?

A. It varied depending on the company. Pierre Fabre was the most interested, and Servier was probably the least interested.

Q. And what indicated to you that they had a level of interest?

A. Their knowledge of the cholesterol-lowering

marketplace and the types of questions that they asked. Pierre Fabre was very knowledgeable in the area of niacin and in the lipid-lowering field in general.

Q. And how did you leave it with these companies as far as what was to happen next?

A. All future communication would go through Ms. O'Neill.

Q. Did they give you any sense of time frame as to when they would be communicating with Ms. O'Neill?

A. It ranged from approximately a month to several months.

MR. CARNEY: Your Honor, I've reached another natural breaking point if you wish to take a break.

JUDGE CHAPPELL: Okay, let's take a break for 15 minutes. We'll recess until 11:35.

(A brief recess was taken.)

JUDGE CHAPPELL: Mr. Carney, you may continue.

MR. CARNEY: Thank you, Your Honor.

BY MR. CARNEY:

Q. When we broke, we were just wrapping up with the European presentation. Do you know if those companies signed a confidentiality agreement with Upsher-Smith?

A. Yes, they had to prior to my presenting the clinical safety and efficacy information.

Q. After you came back from Europe, did there come a time when you became aware that Upsher-Smith had found a European -- a licensing partner for Niacor-SR?

A. Yes.

Q. And who was that partner?

A. That partner was Schering-Plough.

Q. And do you recall when that was?

A. Sometime in June.

Q. What was your involvement with that license agreement?

A. I had little, if any, involvement. The only thing I did was review some trade names, names that FDA has, you know, established specific ways to say the name for Paul Kralovec.

Q. Do you recall what products those were?

A. Those were Klor Con 8 and 10, our wax matrix product, pentoxifylline, Prevalite and the Niacor-SR.

Q. What effect, if any, did the fact that Schering was licensing the product have on your work on Niacor-SR in the summer of '97?

A. It had no effect.

Q. And why was that?

A. Because we were going forward with our NDA and the primary activity was to complete the final study reports and the ISS/ISE.

Q. And did you have any communications with anyone at Schering at that time?

A. Yes, I did.

Q. And who did you communicate with?

A. Jim Audibert.

Q. Do you know what his position is?

A. I don't know his exact title, no.

Q. And do you remember how you communicated with him?

A. Via fax and telephone.

Q. Do you remember how many communications you had with him?

A. No, we had several, but I don't know the exact number.

Q. May I ask you to turn in the exhibit binder to what is marked as the next tab, USX 189, ask you to identify that document.

A. That is a fax from Mr. Audibert to myself.

Q. And do you remember receiving this fax?

A. Yes, I do.

Q. And do you recall -- do you see in the first sentence where it says, "Mark, as a follow-up to our recent discussions, I would like to arrange a meeting at Upsher-Smith for the week of September 15 so that our regulatory and clinical people can meet with you to

review the Niacor-SR dossier and discuss filing strategies."

Do you recall your having discussions with him prior to this August 14 fax?

A. I had some discussions, yes.

Q. And do you remember what it was you discussed?

A. We discussed the final study reports.

Q. Which study reports were those?

A. The reports for our two pivotal trials and for our two follow-on studies.

Q. And then further down it says, "Please let me know which day of that week would be best. It is important that we schedule a meeting that week as that is the only time in September and October that our head of European Regulatory is available."

Did you have any discussions with him prior to this fax about that meeting?

A. Yes, that was part of the discussions.

Q. And when you received this fax, what did you do, if anything?

A. Actually, we talked again, and we did not have the final study reports complete at that point in time, and so we weren't ready for a meeting on this week of September 15th.

Q. Do you recall what you had ready or available

at that time?

A. Specifically what was ready, no. We were -- we had draft results, but we did not have what we considered to be clean data. We had to dot some Is, cross some Ts, and we felt we needed that prior to meeting with their group.

Q. Do you know at this time, the July-August time frame, what Upsher-Smith's plan for its NDA was?

A. We were planning to file the NDA here in the States.

Q. And do you remember the time frame that you were planning to file it in at that time in July-August of '97?

A. By the end of the year.

Q. And that's the end of 1997?

A. Correct.

MR. CARNEY: Your Honor, at this time I'd like to move for the admission of USX 189 into evidence.

JUDGE CHAPPELL: Any objection?

MS. BOKAT: No, Your Honor.

MR. RAOFIELD: No, Your Honor.

JUDGE CHAPPELL: USX 189 is admitted.

(USX Exhibit Number 189 was admitted into evidence.)

BY MR. CARNEY:

Q. Do you recall if you sent anything out -- if you had any further communications with Mr. Audibert about this October 14th communication?

A. Yes, I did. I requested that one of my staff members send him the protocols for the four studies.

Q. And why did you do that?

A. Because that would provide them with some information, since the final study reports weren't complete at that point, that they could start digging into how we studied the drug.

Q. And can you turn to the next exhibit, USX 727 in the binder. Can you identify that once you have had a chance to look at it?

A. That's the cover letter from one of my staff members, Marge Garske, sending the protocols to Mr. Audibert.

Q. And do you know which protocols those were?

A. Those were the two pivotal trials, the 115 and the 221, and the follow-on studies, the 837 and 944.

Q. And do you know if Ms. Garske had any other communications with Mr. Audibert?

A. She may have. I believe he asked for some additional information.

Q. Do you recall what that information was?

A. It had to do with the clinical investigators,

the physicians who were studying our medication.

Q. Can you turn, please, to the next exhibit, which is CX 366, and could you identify that document, please?

A. That's the actual letter from Mr. Audibert requesting information on our investigators.

Q. Did you have any objections to Ms. Garske providing this information to Mr. Audibert?

A. No.

Q. Do you recall if you asked her to provide it?

A. No, I don't. I don't recall.

Q. Do you remember any other communications you had with individuals at Schering-Plough in this time frame?

A. Mr. Audibert was the only person I communicated with.

Q. Okay. If you could turn to the next document, please, which is Bates labeled USX 361, and it's a fax, and I think the second page is clearer than the first, if you could look at it and once you've had that chance identify it for me, please.

A. I've looked at it.

Q. And what is that document?

A. It's a letter from Vickie O'Neill to Mr. Ray Kapur at Warrick Pharmaceuticals regarding

pentoxifylline.

Q. And you're copied on the bottom, do you see that, Mark Halvorsen?

A. Yes.

Q. Do you recall what this concerned?

A. Warrick had asked for a complete copy of our ANDA for pentoxifylline, and at that point -- Warrick is a competitor of ours, and we wanted to only provide them with the information that was necessary to obtain approval in Europe and not necessarily the entire ANDA.

Q. And pentoxifylline is one of the drugs you said you reviewed that was on the license agreement list?

A. That is correct.

Q. What is pentoxifylline?

A. It's a generic for the brand name Trental. It's for intermittent claudication.

Q. What does that mean?

A. What that is is it's -- in the periphery, as you get decreased sizes of your arteries, blood cells have a hard time getting and giving oxygen to those tissues, and it actually allows red blood cells to be more flexible and to make it through the tighter spaces and deliver oxygen.

Q. And were you involved at all in responding to -- in connection with providing information to

Schering-Plough regarding pentoxifylline?

A. I had a concern about providing them with the entire ANDA, and I had expressed that to Vickie, so that she could then find out which important parts they needed.

Q. And what was your concern at the time?

A. Just that they were a competitor, and I didn't want them to have the entire ANDA and see how we put things together that might give them an advantage. I just wanted to provide them with the necessary information.

Q. And in your view, what would the necessary information be?

A. The biostudy.

Q. In October of '97, what was the approval status of Upsher-Smith's ANDA for pentoxifylline?

A. In October, it was not approved yet.

Q. And do you know why it was not approved at that time?

A. Yes. In July of '97, we had received a letter from the FDA stating that one of our bioequivalent studies was not acceptable.

Q. Okay. Let me take you back to June of '97. Had the ANDA been filed at that time?

A. Oh, yes.

Q. And did you as director of clinical at Upsher-Smith have any expectation as to when it was going to be approved?

A. I was expecting it to be approved in the first round of approvals, which was early July.

Q. And when you say the first round of approvals, what do you mean by that?

A. That was when the exclusivity for the innovator drug, the Trental, expired.

Q. So, you expected to be -- you expected pentoxifylline to be approved upon the expiration of the innovator. Is that correct?

A. That's correct.

Q. And that was for July of '97?

A. Yes, it was.

Q. And when did you find out that that wasn't going to happen?

A. Well, at the time the first generics were approved, two or three days thereafter, we received a letter from the agency saying our one bioequivalence study was not acceptable.

Q. So, that was July of '97, you were told your study was not acceptable?

A. That is correct.

Q. And did you eventually get approval for

pentoxifylline?

A. Yes, we did.

Q. And when did that occur?

A. That didn't occur until 1999. We had actually made some arguments to the FDA. They did not agree with our arguments to accept our study. We went and repeated the study, and one week before we were submitting this entire repeated study, they decided to accept our original study, and they gave us approval then.

Q. So, in October 1999, they told you that the study that they had rejected as deficient in July was, in fact, sufficient for approval?

A. Yes, they changed their mind and decided it was acceptable.

Q. Do you know how much -- how much of a delay in total that was for Upsher-Smith as far as getting the product onto the market?

A. It was over a year delay.

Q. But in June of '97, you thought you were going to get the product on the market when?

MS. BOKAT: Objection, leading.

MR. CARNEY: I think it asks him when, Your Honor.

JUDGE CHAPPELL: Overruled. He's not

suggesting an answer. He asked when.

THE WITNESS: I expected to receive approval when the first -- when the exclusivity expired with some of the first products in July of '97.

BY MR. CARNEY:

Q. Okay, I am going to shift here a little bit and ask you to get out the blue binder there, Volume 23, USX 1146 to USX 1266, there are a couple of exhibits in that binder.

If you could turn, please, to USX 1188, and we were talking about these exhibits earlier, and I think you said they were the conference calls minutes and agendas, and this is one that is dated July 22, 1997, and if you could turn to the -- if you could turn to the second page, do you see where it says, "Attendees: USL, Mark Halvorsen"? That means you were on this phone call?

A. Yes, I was.

Q. And if you'd turn to the last page where it says, "VI, Other Issues, A, Timelines, October 31, 1997 is NDA submission date," what did that mean?

A. That was the date that we were looking to have everything completed to file this NDA.

Q. And that's the Niacor-SR NDA?

A. That is correct.

Q. Okay. And then if we move forward to USX 1190, and this appears to be another conference call, August 8, 1997, and if you'd turn to the last page of this August communication, you've got VI, Other Issues, and then it says, "Major decisions are being made by USL regarding NDA submission. Niacor competitor received approval this week and this may affect NDA strategy."

What did that refer to?

A. That was referring to the approval of Kos' Niaspan product.

Q. And why had you told -- why had this been included in the conference call?

A. Because that was an important event. They were our main competitor, and ClinTrials knew that they were our main competitor, all our CROs knew that, and we were under a time constraint. So, we were watching Kos, and it was going to be a major item we needed to discuss internally at Upsher-Smith.

Q. Okay. And then moving to USX 1192, this is another fax dated August 11, 1997, and the second page says "Minutes," and then if you turn to the last page where it says, "VI, Other Issues, Competitor's approval will not affect the current plan for submission," what's that referring to?

A. It remains a -- it basically is informing our

CROs that we had reviewed the approval of Kos' Niaspan product, and that was not going to affect our current plan for the NDA submission.

Q. Okay, and I'm going to skip forward in time a bit more to USX 1216, and this is a fax that says, "Minutes," on the front, October 24, 1997, and this is page Upsher-Smith-FTC-093521, and at the bottom, under 920944, "A, Analysis Update," and the second bullet point -- are you with me here? Okay, "Daily conference calls have been scheduled with NT during their review of the draft tables."

Who is NT again?

A. NT is NovaTech Sciences, our statistical CRO.

Q. And what's this referring to?

A. They were having daily conferences with ClinTrials Research at that time, because we really wanted to meet our time lines, and in order to do that, we needed to set up daily calls.

Q. And this was in the fall of '97 -- withdraw that.

I'll move forward to USX 1226, and this takes us to a December 16, 1997 fax, and do you see the first page says, "Minutes"? And then on the second page -- well, on what is the third page of the fax, it says, "VI, NDA," and down at the bottom here of

Upsher-Smith-FTC-093953, the third bullet point under NDA says, "Mark Halvorsen informed the team that although USL is not going forward with filing the NDA there is a possibility that they will proceed in Europe."

What was this referring to?

A. At that point in time, Upsher-Smith had made the decision that filing the NDA in the United States, we had decided not to do that.

Q. And what was it referring to as to the possibility that they will go forward in Europe?

A. Is that we had a European partner in Schering-Plough and that they most likely would go forward.

Q. Okay. And then moving forward in time to USX 1235, a fax dated January 12, 1998, and the first page -- the second page says, "January 9, 1998 Minutes," and if you turn to the next page, do you see where it says, "IV," at the bottom, and it says, "ISS (115, 221)," what does that refer to?

A. That's integrated summary of safety.

Q. And that was an independent discussion item in these minutes?

A. Yes, it's really the compilation of the safety information contained within your clinical trials.

Q. And then at the very bottom there's a bullet point, the second one out towards the margin, and it says, "Draft tables - date to be determined. USL will be providing the ISS draft tables to their European partner. NT will QA the draft tables."

What does "QA" mean?

A. Quality assurance. It means reviewing the tables for accuracy.

Q. And why were you informing ClinTrials that you would be providing the ISS draft tables to your European partner?

A. Because we expected the partner to go forward, and we needed to live up to our commitment to provide all of the documentation.

Q. What was the status of Upsher-Smith's NDA at this time internally at Upsher-Smith?

A. Upsher-Smith had determined that we would not go forward with the NDA in the United States.

Q. And do you know what the status of the ANDA project was?

A. At this point, we had discontinued the ANDA project as well.

Q. But you were still communicating with ClinTrials about all this work?

A. Yes.

Q. And then I'm going to skip forward a bit more to -- in time to USX 1258, and this is a fax dated March 26, 1998, and the second page says, "Agenda, March 27, 1998," and it's got handwriting on it.

Do you recognize the handwriting there?

A. Yes, that's my handwriting.

Q. And did you -- do you recall why you wrote on this document?

A. Yes, it was to document that I had notified the CROs that our European partner, or Schering, was not going to pursue their submission.

Q. Okay. Are you looking at the what is the third page of the fax, Upsher-Smith-FTC-093868?

A. Yes, with Roman numeral V, the ISS.

Q. It says, "Notified CTR that European partner will not pursue submission," is that what you're referring to?

A. Yes, I am.

Q. Do you know when you wrote this on the document?

A. During the teleconference.

Q. Was that your practice?

A. Yes, I would take notes on the agendas.

Q. And then if you would skip to USX 1260, a fax dated March 27, 1998, do you see the second page says,

"March 27, 1998 Minutes"?

A. Yes.

Q. And then on the next page, point IV, "ISS (115, 221), A, Analysis Update," and then in that paragraph, do you see where it says, "M. Halvorsen informed us that this will be the final iteration for the tables. USL's European partner has decided not to proceed with the drug."

Do you recall what that was relating to?

A. That was the typed minutes of what I had told them during the teleconference.

Q. And earlier I believe you testified that this was your understanding based on a meeting at Upsher-Smith?

A. Yes.

Q. And the last sentence in that paragraph says, "M. Halvorsen confirmed that 'draft' is acceptable on the tables."

What's that relating to?

A. It's meaning that we had not actually completed the ISS, and we would take to -- through QA process or reviewing of the data, and we would expect the draft as is.

Q. And then if you move to Exhibit USX 1263, this is April of 1998. It says, "Minutes," and then on the

second page, you've got under point III, 920944, point B, "Analysis Update, Per M. Halvorsen, the draft tables will be considered Final."

Why was the draft table to be considered final?

A. At this point, since Upsher-Smith was not going forward in the United States and Schering was not going forward in Europe, we were wrapping up the activities.

Q. And at the bottom where it says V, "ISS (115, 221)," there's a paragraph under Analysis Update, the third sentence, "Per M. Halvorsen, life table analyses will not be run. ISS is essentially done and there will be no review of the tables."

What's this referring to?

A. It's referring to the fact that we would accept the tables as they were and we were not going to perform QA and that we would not actually complete the life table analysis.

Q. And then moving to USX 1265, a fax dated May 19th, 1998, it says on the second page, "Agenda," and then under I, where it says 920115, point A, it says, "CRFs - 91 boxes - projected date to ship 5/22."

What did that refer to?

A. As part of record retention, we need to keep the case report forms, which is what CRF stands for, that's the data page where the information regarding

individual patients is entered, and ClinTrials, as part of the wrap-up, was sending all of the paper documentation back to us for storage.

Q. And then at point IV, it says, "920837, A, Data Management Update," and then it talks about, "1, Final coding with sign-off."

What was that referring to?

A. The 837 study was our lowest priority study, had the smallest number of patients. So, we hadn't gotten into working on the actual final report. We were just up to locking the database.

Q. And then point V, "Other, USL, please confirm the address for shipping," and then it has Upsher-Smith Laboratories and an address below that.

What was that related to?

A. That's where all of the pallets of documents were to be shipped.

Q. And when you say "pallets of documents," what are you referring to?

A. The wooden shipping pallets. We filled up a lot of them with paper documents. They shipped probably about a truckload to us.

Q. And what were those documents?

A. Those were all of the case report forms for every single patient that had been enrolled in any

study, and then all of the subsequent data analyses, draft reports, final reports, everything associated with our investigation of Niacor-SR.

Q. And did that include final study reports as well?

A. Yes.

Q. And ISS information?

A. Yes.

Q. And ISE information?

A. I believe so.

Q. Do you know in total about how many boxes were sent to Upsher-Smith with this information?

A. Several hundred.

Q. Once they got to Upsher-Smith, what happened to this information?

A. We had to integrate our in-house information with this documentation and fully store the product, all of the information, whether it be study medication that was used for the product, our internal communications with each of the investigational sites, just it's integrating all of the documents that are generated in the study.

Q. How much internal information was there in the Clinical Research Department at Upsher-Smith?

A. A lot. Multiple five-drawer, 48-inch-wide file

cabinets, we had pallets in our warehouse, I think we ended up with about 30 pallets of documents.

Q. Any sense of how many boxes of documents you can get on a pallet?

A. Maybe nine or ten per level and then four levels, so about 40 boxes.

Q. Do you know what the total amount of money was that Upsher-Smith spent on Niacor-SR through the end of 1998?

A. $14 to $15 million.

Q. In your career at Upsher-Smith, what has been the most time-consuming clinical project you've worked on?

A. Niacor-SR.

Q. And when Upsher-Smith eventually decided not to go forward with Niacor-SR after spending all that money, in your experience, was that unusual?

A. No. Companies can walk away from a product at any stage of development. When I was at Hoffman-LaRoche, we had spent several hundred million dollars preparing a product, filing the NDA, and we actually received approval for it, and we never marketed the product.

Q. Do you know why that product was never marketed?

A. Because it was what's called a me-too product, meaning it was in a category of drugs, some quinoline antibiotics, that there were several products, approximately eight or nine, on the marketplace already, and there was nothing unique about our product. So, for us to gain a niche or be able to sell it, you had nothing to rely upon. It was just another same old quinoline.

MR. CARNEY: Thank you, Dr. Halvorsen.

I have no further questions at this time, Your Honor.

JUDGE CHAPPELL: Any cross?

MS. BOKAT: Yes, please, Your Honor.

JUDGE CHAPPELL: What about the matter of the exhibits that were offered and we have a pending objection?

MR. CARNEY: We didn't have an opportunity to discuss that at the break. I thought they might want some time. I'm sure we'll confer and hopefully reach a result today.

JUDGE CHAPPELL: Okay, thank you.

MR. RAOFIELD: Your Honor, I have two very brief questions on behalf of Schering. I don't mind waiting until after cross --

JUDGE CHAPPELL: This is direct exam, right?

MR. RAOFIELD: Sure, yes, Your Honor.

JUDGE CHAPPELL: You may proceed.

Do you object to that, Ms. Bokat?

MS. BOKAT: I do not, Your Honor.

JUDGE CHAPPELL: Go ahead when you're ready.

DIRECT EXAMINATION

BY MR. RAOFIELD:

Q. Good morning, Dr. Halvorsen.

A. Good morning.

Q. Again, I'm Jason Raofield on behalf of Schering. I know we've met before, met at your deposition. I just have a couple quick questions for you.

You were just speaking with Mr. Carney about the process of archiving the documents and gathering the documents after you terminated the NDA project. Do you recall that?

A. Yes.

Q. And Mr. Carney was going through the binder with you up through the May 1998 period where you were collecting the materials from the third parties. Do you recall that?

A. Yes.

Q. And you said that subsequent to that period, Upsher-Smith had some work to do internally to complete

that process of collecting and storing those materials. Do you recall that?

A. Yes.

Q. I'd like to show you a document, and I apologize, I only have one copy, so I'm going to try to put it up on the screen here.

This is a document dated -- it appears to be dated August 12th, 1998. It appears to be an e-mail from Marge Garske to Mark Halvorsen. Do you see that?

A. Yes.

Q. If you could take a look at the subject, it says, "Archiving of Niacor ISS files." And if you look at that e-mail, does this e-mail relate to the internal Upsher collection of materials that you were speaking of before?

A. Yes.

Q. And so this would indicate that as of August 12th, 1998, the e-mail was sent to you on this subject?

A. Yes.

Q. And the e-mail reads, "Next Tuesday, I plan to start the process of listing the files of the ISS materials leading to their subsequent archival."

Do you see that?

A. Yes.

Q. And would that indicate to you whether you had

completed this process as of August 12th, 1998?

A. For archiving the ISS files, it appears that we had not finished the archiving of that grouping.

MR. RAOFIELD: Your Honor, this document may be admitted into evidence as an exhibit number already. I don't have that. However, at this time, to be safe, I would move for the admission of the document, and I'd be happy to check on that and withdraw it if it -- if it does cause an overlap.

JUDGE CHAPPELL: You are going to have to have a number on it if you offer it, Mr. Raofield.

MR. RAOFIELD: Yes, Your Honor, could I take care of that and clean up this matter at the end of complaint counsel's cross examination or as we finish with this witness?

JUDGE CHAPPELL: Why don't we see if we have an objection to it.

MR. RAOFIELD: Yes, Your Honor.

MS. BOKAT: I don't have a copy of it, I don't believe.

MR. RAOFIELD: I can certainly get a copy. I think the answer is going to be that it's already on the list. It's just that there are roughly over a thousand documents. I haven't had a chance now --

JUDGE CHAPPELL: So, I interpret your request

as one to offer this later rather than now.

MR. RAOFIELD: Yes, Your Honor.

JUDGE CHAPPELL: All right.

BY MR. RAOFIELD:

Q. Mr. Halvorsen, just one other subject very briefly. If you take a look at the smaller of the three binders that were used during your examination, there was some discussion regarding the PK study. Do you recall that?

A. Yes.

Q. And there was discussion regarding the protocol at SPX 0331, if you could take a look at that.

A. Um-hum.

Q. During your testimony, I believe you referred to the PK study and were asked questions about it and you said it was relatively easy to do. Do you recall that testimony?

A. Yes.

Q. I'm going to direct your attention to the third page of the document, which is labeled Upsher-Smith-FTC-111279, and specifically to the top of that page, 3.1, Summary. Do you see that?

A. Yes.

Q. And it says, "This is a single-dose, open-label, randomized, four-way crossover study.

Healthy adult male and female subjects will receive a single dose of niacin (immediate-release or extended-release) four times during the study."

Now, I believe in your testimony you referred to this and you made reference to the fact that these were subjects and not patients. Do you recall that?

A. Yes.

Q. Could you explain what that distinction is?

A. A subject is a healthy individual that does not have the disease state related to the drug. All you're asking them to do is come in and take a single dose of the medication and have blood drawn.

Q. As opposed to?

A. As opposed to a patient that you're treating for your disease state, that you need to make sure they have the disease state and make sure that they would be appropriate candidates for long-term therapy with your medication.

Q. So, when you're conducting a study that requires that you enroll healthy subjects rather than patients who have, you know, a known condition, does that have any impact on the level of effort required to locate and enroll those patients?

A. Oh, they're easy to enroll, just locate it near a college, and you can recruit college students just

very easily.

Q. And the last sentence in that paragraph says, "The subjects will remain in the clinic for the entire length of the study (17 days)."

Do you see that?

A. Yes.

Q. And is that consistent with your recollection as to the length of the study for this protocol?

A. Yes, this study is very short, even shorter than some of our bioequivalence studies.

Q. And 17 days is a little over two and a half weeks. Is that your understanding?

A. Yes.

Q. How does that compare to the length of the studies for the Niacor-SR pivotal trials?

A. Treatment in the clinical safety and efficacy trials were 33 weeks for a single patient, and then we had to enroll all of the patients into that study. So, the treatment period of -- in our clinical trials went over a year.

Q. And finally, under 3.2, Number of Subjects, the first sentence there reads, "Thirty-two healthy adult male and female volunteers and 6 alternatives will be enrolled."

Do you see that?

A. Yes.

Q. And is that consistent with your recollection as to the number of subjects for this study?

A. Yes.

Q. And how does that compare to the number of subjects in the Niacor-SR pivotal trials and follow-on trials?

A. I believe I discussed the pivotal -- two pivotal trials had approximately 900 patients enrolled, and the follow-on studies had approximately 300 patients enrolled.

Q. Okay. And I think my last question, I missed it, in the second sentence under 3.1 was -- it referred to the healthy adult male and female subjects, and then at the end of the sentence, it goes on to say, "will receive a single dose of niacin four times during the study."

Do you recall that?

A. Yes.

Q. How often were subjects dosed in the Niacor-SR pivotal studies?

A. In the pivotal studies, they took the medication twice a day, so they're taking medication twice a day for 33 weeks.

Q. And this refers, when it says four times during

the study, it's talking about four times during the entire 17-day period?

A. A single dose of medication four times during the study.

MR. RAOFIELD: Thank you very much. No further questions, Your Honor.

JUDGE CHAPPELL: Ms. Bokat?

MS. BOKAT: Yes, Your Honor.

CROSS EXAMINATION

BY MS. BOKAT:

Q. Good afternoon, Dr. Halvorsen.

A. Good afternoon.

Q. Mr. Halvorsen, excuse me.

In February or March of 1997, the FDA asked Upsher-Smith to do a three or four arm PK study on Niacor-SR, did it not?

A. That is correct.

Q. Upsher-Smith representatives and the FDA actually met to discuss that PK study in February or March. Isn't that correct?

A. That is correct.

Q. The FDA requested that PK study in order for Niacor-SR to get an extended release indication, correct?

A. That is correct.

Q. And at that time, Upsher-Smith was planning to seek an extended release indication for Niacor-SR, correct?

A. Correct.

Q. And you talked earlier today about the protocol that Upsher-Smith actually sent to the FDA for that PK study, right?

A. Yes.

Q. Upsher-Smith kept all its correspondence with the FDA about Niacor-SR, did it not?

A. Yes.

Q. Those files were kept by your department, weren't they?

A. The regulatory affairs department, yes.

Q. Which is your department.

A. Yes, one of my two.

Q. Did you also in your department keep copies of all minutes of meetings with the FDA about Niacor-SR?

A. Yes, we did.

Q. If Schering-Plough in June of 1997 had asked for access to those files of correspondence and meeting minutes with FDA, your department would have been able to provide them, would they not?

A. Yes.

Q. If Schering had made a request for access to

the files of communications with FDA, that request would have come into your department, would it not?

A. Correct.

Q. In June of 1997, prior to June 17th, Schering didn't make any request for access to those files of communications with the FDA about Niacor-SR, did they?

A. Correct. Jim Audibert did request that we meet with the European regulatory individual.

Q. But that was after June 17th of 1997, wasn't it?

A. Correct.

Q. As of June 1, 1997, Upsher had a draft report of that pivotal 115 study, did it not?

A. Correct.

Q. As of June 1st, 1997, did Upsher have at least a draft of the 221 study?

A. We had draft data. I don't know if we had an actual draft report. I don't think we actually had a draft report in place.

Q. If Schering had asked for a copy of the draft report on the 115 study, that request would have come to your department, would it not?

MR. CARNEY: Objection, hypothetical, Your Honor.

JUDGE CHAPPELL: Overruled. She's not asking

for any kind of an opinion, just for an answer, so I'll overrule it.

MR. CARNEY: Yes, Your Honor.

THE WITNESS: Would you repeat the question, please?

MS. BOKAT: Would it be all right if she read it back, Your Honor?

JUDGE CHAPPELL: Yes.

(The record was read as follows:)

"QUESTION: If Schering had asked for a copy of the draft report on the 115 study, that request would have come to your department, would it not?"

THE WITNESS: Correct.

BY MS. BOKAT:

Q. Did Schering ask before June 17th, 1997 for the draft report of the 115 study?

A. No.

Q. If Schering had asked for the draft data from the 221 study, that request would have come to your department also, would it not?

A. Possibly. I wasn't involved with the negotiations with Schering, so it may have come through another department or another individual.

Q. That draft data, that is, the draft data for the 221 study, was that located within your department?

A. I had a copy, and others had copies within the company.

Q. Are you aware of Schering asking prior to June 17th, 1997 for the draft data from the 221 study?

A. I am personally not aware of that.

Q. From January 1st to June 17th of 1997, did you personally meet with anyone from Schering-Plough?

A. I did not.

Q. From January 1st to June 30th of 1997, did you personally have any communications with anyone from Schering-Plough?

A. I don't know when my first conversation was with Mr. Audibert, the exact date.

Q. Do you think it was before June 17th, 1997?

A. I don't know.

MS. BOKAT: Your Honor, may I approach the witness, please?

JUDGE CHAPPELL: Yes, you may.

MS. BOKAT: May I approach the Bench?

JUDGE CHAPPELL: I don't need that if it's going to be on the ELMO.

MS. BOKAT: Okay, with Ms. Hertzman's assistance, I think I can get it on the ELMO. If I fail, I'll come back, okay?

JUDGE CHAPPELL: Well, since you're here, I'll

take it.

BY MS. BOKAT:

Q. Mr. Halvorsen, do you recall my taking your deposition in October of last fall?

A. Yes, I do.

Q. One of your more fun experiences?

A. A wonderful experience.

JUDGE CHAPPELL: Now, that called for an opinion.

BY MS. BOKAT:

Q. I'm going to ask -- if you could put that up on there, please.

Mr. Halvorsen, during that deposition, did I ask and did you answer:

"QUESTION: I asked you whether you had had any meetings with people from Schering-Plough between January 1 and June 30, 1997. I neglected to ask you but I'd like to ask you now whether you had any phone calls or correspondence between January 1 and June 30, 1997, with anyone at Schering-Plough?

"ANSWER: During that period? I don't believe so. I don't fully recall."

Do you recall today whether between January 1st and June 30th, 1997, you had any phone calls or correspondence with anyone at Schering-Plough?

A. I don't recall.

Q. Focusing now just on the five or six-day period between June 12th and June 17th, 1997, in that time period, did you have any communications with anyone at Schering-Plough?

A. I don't know. I don't remember those specific dates. I can't pinpoint something to an exact date.

Q. But you don't recall having any communications in that time period. Is that right?

A. I don't recall.

Q. At the time of the settlement negotiations between Upsher-Smith and Schering-Plough, you weren't aware of those negotiations, were you?

A. No, I was not.

Q. Going back to the 115 study on Niacor-SR for a moment, that study had a dropout rate of 35.7 percent, did it not?

A. Yes, it did.

Q. The PK study on Niacor-SR that the FDA requested in February or March of 1997, Upsher had outside companies working on the method development. Is that right?

A. Correct.

Q. As of June 12th, neither company had completed developing the method for the PK study, had it?

A. That is correct, they were waiting to receive samples from a pilot study so they could fully evaluate the lower limit of quantitation, called the LLOQ, the lowest level where you can detect the drug.

Q. So, as of June 12th, the PK study hadn't even begun, right?

A. I don't know the exact date. The pilot study may have already started.

Q. But the actual PK study did not start.

A. The actual one for submission to the FDA had not yet started.

Q. Schering didn't inquire prior to June 17th about the status of that PK study, did it?

A. Not that I recall. I don't have a best memory of that.

Q. Do you have any memory of them -- of Schering doing so?

A. I don't recall.

Q. You were talking earlier with Mr. Carney about James Audibert in August 1997 requesting the clinical reports from the studies on Niacor-SR. He requested clinical reports on all four protocols?

A. Yes.

Q. Schering hadn't requested the clinical reports from those four Niacor-SR studies before Mr. Audibert's

request in August of 1997, had it?

A. Not from me personally.

Q. Upsher-Smith actually provided the four protocols to Schering, did it not?

A. Yes.

Q. But you didn't supply final study reports, correct?

A. No, the reports were not finished. They weren't -- all the Is weren't dotted, all the Ts weren't dotted, and when I discussed that with Mr. Audibert, we delayed and he wanted to see the final reports.

Q. So, Mr. Audibert asked for the reports in August and got the protocols, and then he made one more request for clinical data in October 1997, didn't he?

A. I believe so.

Q. After that October request, there were no further requests from Schering for clinical reports from the Niacor-SR studies, were there?

A. Not to me personally.

Q. No one from Schering ever visited Upsher-Smith's facilities after the settlement agreement was signed in June, did they?

A. I don't know that. I believe that there was a facility audit for one of the products. They did not

personally meet with me.

Q. Mr. Halvorsen, would you be kind enough to look back at the transcript you were looking at a couple minutes ago, and during your deposition, did I ask:

"QUESTION: Were you aware of anyone from Schering-Plough making any visits to Upsher-Smith's facilities after Upsher-Smith and Schering-Plough agreed to the Niacor-SR license?"

A. What page are you on?

Q. I am on page -- I'm on 166, and whether I can get the ELMO to there without technical assistance remains to be seen.

This is page 166, sir, beginning at line 20.

JUDGE CHAPPELL: Mr. Raofield, you might want to move up to counsel table so she can see you stand up if you need to object.

MR. RAOFIELD: Yes, Your Honor.

JUDGE CHAPPELL: Did you still have an objection?

MR. RAOFIELD: No, I was just looking for a page cite, Your Honor, it hadn't appeared on the screen.

BY MS. BOKAT:

Q. Did I ask you, Mr. Halvorsen:

"QUESTION: Were you aware of anyone from

Schering-Plough making any visits to Upsher-Smith's facilities after Upsher-Smith and Schering-Plough agreed to the Niacor-SR license?

"ANSWER: I don't personally recall anyone visiting, but I know there were requests for others --"

JUDGE CHAPPELL: Hang on Ms. Bokat. Your question was did I ask you, so I think you need to stop after the question you read.

THE WITNESS: Yes, you did ask that question.

JUDGE CHAPPELL: Thank you.

BY MS. BOKAT:

Q. Did you answer -- ah, now I've got to go back to the ELMO again.

"ANSWER: I don't personally recall anyone visiting, but I know there were requests for others to meet with Schering-Plough representatives outside of myself and I can't speak for them."

Is that still your answer today, sir?

A. I did subsequently find out that the other departments did meet with someone. Whether it was a Schering or a Warrick representative, I don't know.

Q. You found that out subsequent to your deposition?

A. Yes, as reviewing documentation.

Q. The reports of the clinical studies on

Niacor-SR were the only information that Mr. Audibert sought from you. Isn't that right?

A. That is correct.

Q. The pivotal studies on Niacor-SR were designed for twice-a-day dosing, were they not?

A. That is correct.

Q. So, Niacor-SR would be approved only on twice-a-day dosing, correct?

A. If we went forward with the current NDA as the original plan was, yes.

Q. So, Niacor-SR could be promoted only for twice-a-day dosing, correct?

A. That is correct.

Q. Whereas Kos' Niaspan had an indication for once-a-day dosing, did it not?

A. Correct.

Q. In the late 1997, early 1998 time frame, Upsher-Smith had internal discussions about whether to pursue the NDA for Niacor-SR, correct?

A. Correct.

Q. You participated in those discussions, did you not?

A. Some of them, yes.

Q. Representatives from Schering-Plough didn't participate in those discussions, did they?

A. No, that was for our internal NDA.

Q. Were Schering representatives invited to participate in those discussions?

A. No, that was for Upsher-Smith's NDA within the United States, where Schering-Plough had the European marketing rights.

Q. But Schering-Plough was to have access to your NDA if it was ever filed, correct?

A. They would have access to all of the final study reports and the ISS and ISE, which were part of our application and which we continued work even after we discontinued the NDA for the United States.

Q. In the late 1997, January of 1998 time frame, Upsher-Smith didn't inform anyone at Schering that they were considering not pursuing the NDA, did they?

A. For our internal development, they had no rights to the United States, and we continued with the study reports as they would need.

Q. So, the answer to my question is no?

A. We didn't need to notify them regarding our United States decisions.

Q. The question is, did you notify them?

A. Oh, no.

MS. BOKAT: May I approach the witness, Your Honor?

JUDGE CHAPPELL: Yes.

MS. BOKAT: We should be able to get this document up on the computer.

JUDGE CHAPPELL: Then I don't need it.

MS. BOKAT: Okay.

BY MS. BOKAT:

Q. September 1998 was the first time Upsher-Smith informed Schering-Plough that they were not going forward with the NDA on Niacor-SR. Is that correct?

MR. CARNEY: Objection, foundation, Your Honor.

JUDGE CHAPPELL: Sustained.

BY MS. BOKAT:

Q. Mr. Halvorsen, do you know when Upsher-Smith first informed Schering-Plough that Upsher-Smith was not going forward with the NDA on Niacor-SR?

A. I do not.

Q. The indications that Niaspan had and that Niacor-SR would not have were reducing the risk of recurrent heart attack and regression of arthrosclerosis, correct?

A. Those are the basic terms. You didn't get them right, but they're close enough.

JUDGE CHAPPELL: Ms. Bokat, are you finished with this exhibit?

MS. BOKAT: Yes, I am. Thank you for the

reminder.

BY MS. BOKAT:

Q. One of the reasons Upsher-Smith stopped working on its NDA for Niacor-SR was that Niacor-SR was not going to have those two indications, correct?

A. That was one of the primary reasons, yes.

Q. As of June 1997, you knew that Niaspan was going to have those two indications, did you not?

A. In June, no.

Q. No? It wasn't until August?

A. I found out when they gained approval sometime in July or when they released what their approve indications were from FDA, on that day or the day after they were approved by FDA.

Q. That information was not in their IPO?

A. I don't believe it was.

Q. In the 115 study that Upsher-Smith did for Niacor-SR, is it your opinion that the dosage of the Niacor-SR was increased too quickly for patients?

A. Yes.

Q. That can lead to excessive adverse events, can it not?

A. Correct.

Q. So, there was a design flaw in that pivotal study, was there not?

A. You could call it a design flaw, but it was just a more conservative approach. The FDA would see more adverse events than what you would see in practice. So, they're seeing a worst case scenario for your approval.

Q. If Upsher-Smith had decided in June of 1997 to redo that study so that the dosage wasn't increased as rapidly, you would have to spend several months with patients in treatment, would you not?

MR. CARNEY: Objection, hypothetical question.

JUDGE CHAPPELL: Response?

MS. BOKAT: This gentleman I think is eminently qualified to answer that question. He supervised all the clinical trials that were done, he supervised all the data review and the report writing. He testified this morning about how much time they had to spend with patients in treatment when they did the original study and how much time they were spending with the subsequent analyses and report-writing work.

JUDGE CHAPPELL: But he's not an expert witness. I'll sustain the objection for the stronger reason that it lacks foundation, that question.

BY MS. BOKAT:

Q. Mr. Halvorsen, did Upsher-Smith consider redoing the 115 study?

A. No.

Q. Was there a reason you didn't consider redoing that study?

A. Yeah, the FDA was very pro-niacin, and the FDA had reviewed preliminary results from our 221 study, the first pivotal study, and they had no concerns.

MS. BOKAT: Your Honor, may I approach the witness, please?

JUDGE CHAPPELL: Yes, you may.

MS. BOKAT: It looks like we do have the document up on the computer.

JUDGE CHAPPELL: Okay.

MS. BOKAT: So I won't burden you with a copy.

JUDGE CHAPPELL: Thank you. It's getting hard to see over the binders up here.

MS. BOKAT: I can sympathize. I was asking for a forklift to get those binders from Mr. Carney this morning.

JUDGE CHAPPELL: That reminds me, you need to retrieve your binders at the end of the day.

MR. CARNEY: I will, Your Honor.

JUDGE CHAPPELL: Thank you. I think we still have some from a few days ago.

MR. CARNEY: I will get those without a forklift, Your Honor.

JUDGE CHAPPELL: Thank you.

BY MS. BOKAT:

Q. Mr. Halvorsen, looking at CX 611, you've seen that document before, have you not?

A. Yes, it's addressed to me.

Q. And that's a letter from --

MR. CARNEY: Your Honor, we object on the basis of beyond the scope. At no time did he discuss Klor Con approval in his direct testimony.

MR. RAOFIELD: Same objection, Your Honor.

JUDGE CHAPPELL: Did you hear him talk about Klor Con?

MS. BOKAT: I heard him talk about Klor Con, but in all honesty, I think that was the 8 and 10.

JUDGE CHAPPELL: Mr. Carney, how did you know it was a question about Klor Con? He was just asked if he has seen that exhibit.

MR. CARNEY: I think the questions were had he reviewed the terms of the license agreement, what were -- what were the drugs that were mentioned there, I think he mentioned it at that time, and it --

MR. RAOFIELD: Your Honor, in light of Your Honor's comment, I will withdraw my objection pending the following questions by complaint counsel.

JUDGE CHAPPELL: We have one withdrawn and

one --

MR. CARNEY: I'll withdraw the objection, Your Honor.

JUDGE CHAPPELL: Okay, so now both are withdrawn. So, you may proceed.

MS. BOKAT: Thank you.

MS. BOKAT: Could the court reporter read back the last question, please?

(The record was read as follows:)

"QUESTION: Mr. Halvorsen, looking at CX 611, you've seen that document before, have you not?

"ANSWER: Yes, it's addressed to me.

"QUESTION: And that's a letter from --"

BY MS. BOKAT:

Q. -- from the Food and Drug Administration?

A. Yes, it is.

Q. Their letter is dated January 28, 1999. Is that right?

A. Yes.

Q. Did you receive it February 1st, 1999?

A. Yes, I did.

Q. That letter informs Upsher that it is eligible for the 180-day exclusivity period for Klor Con M20, does it not?

MR. RAOFIELD: Objection, Your Honor, beyond

the scope of the direct examination.

JUDGE CHAPPELL: Response? Did you hear him talk about the 180-day exclusivity period?

MS. BOKAT: No.

JUDGE CHAPPELL: Well, I haven't had anybody persist in going beyond the scope, but the law according to me, if you're going to take a witness beyond the scope, then it becomes your witness, and you are going to have to use direct examination techniques, and in those areas where you do so, the other side will be able to cross based on your direct. I hope that's not as confusing as it sounds.

MR. RAOFIELD: No, Your Honor.

THE WITNESS: It is to me.

JUDGE CHAPPELL: But that's the fairness doctrine, as I'll call it.

MR. CARNEY: Perfectly clear, Your Honor.

JUDGE CHAPPELL: And with that, do you object to the question if she treats this witness as her own for this purpose?

MR. RAOFIELD: No, Your Honor.

JUDGE CHAPPELL: You may proceed.

MS. BOKAT: Thank you, Your Honor.

JUDGE CHAPPELL: This way we don't need to resubpoena, renotify and continue until July the 4th of

this year. Thank you.

BY MS. BOKAT:

Q. In this letter, what was the FDA informing Upsher-Smith?

A. That we were eligible, as I read from the second page, "Therefore, you are eligible for 180 days of market exclusivity for this product."

Q. And what did you personally, Mr. Halvorsen, take from that letter with respect to the 180-day exclusivity?

A. I was surprised.

Q. What was your understanding from the letter about the 180-day exclusivity as it applied to Klor Con M20?

A. That we would subsequent from approval receive 180 days of market exclusivity for this drug product.

JUDGE CHAPPELL: Ms. Bokat, just for the record, I asked if anyone objected to you proceeding as if this was your witness, and Mr. Raofield said no objection, but I didn't hear from Upsher-Smith.

MR. CARNEY: No objection, Your Honor.

JUDGE CHAPPELL: Thank you.

BY MS. BOKAT:

Q. Mr. Halvorsen, you were talking this morning with -- about two protocols with Mr. Carney. I believe

they're in one of Mr. Carney's big binders. Ah, no, I'm wrong but I'm lucky. It's the skinny one. This is CX 714 and CX 1043.

The protocol that's at CX 714 was a study of once-a-day Niacor-SR dosing at bedtime. Is that right?

A. That's the combination therapy with Niacor-SR and fluvastatin.

Q. That study was never conducted, was it?

A. No, it was not.

Q. The protocol that's at CX 1043, which is the next tab, that was to be done with three different dosing schedules, correct?

A. Correct.

Q. And one of those dosing schedules was to be bedtime dosing?

A. I believe two of them were to be bedtime dosing.

Q. That study was never conducted, was it?

A. No, as I had testified earlier, we had a higher priority, was to file the NDA first and then get to these studies.

Q. So, there were no studies ever done of once-a-day bedtime dosing for Niacor-SR. Is that right?

A. Not as part of the original NDA, no.

Q. Mr. Halvorsen, could we turn, please, to the meetings you had in Europe with I think you said two French companies and two Spanish companies?

A. Sure.

Q. Oh, and we're done with the binder if you want to get that out of your lap.

A. Okay.

Q. During the first week of June 1997, you and Ms. O'Neill met with four European companies about a potential license for Niacor-SR, correct?

A. Correct.

Q. You and Ms. O'Neill were at those meetings -- oh, I'm sorry, you yourself were at those meetings because you were the most knowledgeable about the clinical trials for Niacor-SR, correct?

A. Correct.

Q. The four companies you met with, just to review this, were Servier, Esteve, Lacer and Pierre Fabre?

A. Yes.

Q. Let's start first with Servier. That's one of the French pharmaceutical companies, right?

A. Correct.

Q. You and Ms. O'Neill met with them on June 3rd, 1997?

A. I know it's the first week of June. I don't

know the exact date.

Q. Who attended on behalf of Servier?

A. It was one person. I don't remember the -- it was a physician. I don't remember his name. We met with just one individual.

Q. But he was a physician?

A. I believe so. I addressed him as "Dr."

Q. What were his responsibilities at Servier?

A. I don't recall. I'd have to look at the notes.

Q. Maybe I could find those for you. This way it won't be a quiz.

May I approach the witness, Your Honor?

JUDGE CHAPPELL: Yes, you may.

MS. BOKAT: It looks like Ms. Hertzman got that on the computer for me.

BY MS. BOKAT:

Q. Was it Olivier Arnaud who attended that meeting on behalf of Servier?

A. Yes.

Q. Do you recall what his responsibilities at Servier were at this time?

A. From here his title was listed as director of projects, Scientific Collaboration Division. I believe he was in charge of the science for various projects. I don't recall the specifics.

Q. Dr. Arnaud expressed concern over the elevation in liver function tests among patients in the study for Niacor-SR, did he not?

A. Yes, according to this document, yes.

Q. Did he also raise question about whether the benefits of Niacor-SR in reducing flushing would be a sufficient advantage over the increased risk of LFTs?

A. That's what it states here, yes.

Q. LFTs again are the elevated enzymes in the liver function tests?

A. LFT stands for liver function test.

Q. Dr. Arnaud also questioned whether a company could promote positive effects of Niacor-SR on Lp(a), did he not?

A. Yes, there was at that point in time a very large discussion in the industry that new studies were coming out showing that Lp(a) was an individual risk factor for coronary heart disease, and it was just starting to hit the market with -- in Europe with that information. So, they were still reviewing it, but several studies have been showing now that it is an independent risk factor for cardiovascular disease.

Q. But at that time, June of 1997, Dr. Arnaud questioned whether a company could promote positive effects of Niacor-SR on Lp(a), did he not?

A. According to this, he did, and Europe was a little behind the States in regards to Lp(a).

Q. Schering was going to market Niacor-SR in Europe under the license from Upsher-Smith, was it not?

A. Correct.

Q. At these meetings with the French and Spanish companies, you didn't have Dr. Brown or Dr. Drobnes with you, right?

A. Correct.

Q. So, did you personally do the presentation to these four European companies on both the safety and the efficacy of Niacor-SR?

A. Yes, I did.

Q. Do you recall with Servier how much time you spent on the safety and efficacy issues?

A. The specific amount of time that I used, no.

Q. Do you have a ballpark?

A. I have no idea.

Q. Dr. Arnaud was not attentive during that meeting, was he?

A. That's correct.

Q. Did he seem distracted?

A. That's what's written in the notes here. He just was not really involved with the presentation.

Q. Weren't his lack of attention and his

distractedness an indication that he wasn't very interested in Niacor-SR?

MR. RAOFIELD: Objection, Your Honor, calls for speculation.

JUDGE CHAPPELL: That's sustained. He doesn't know -- he doesn't know about the other gentleman. That's sustained.

BY MS. BOKAT:

Q. We've been talking about this document CX 883. That's a memo from you and Vickie O'Neill, is it not?

A. Correct.

Q. Did Ms. O'Neill prepare this memorandum?

A. Yes, she did.

Q. It's addressed to Mr. Troup and Ken Evenstad, is it not?

A. Correct.

Q. As far as you know, did it go to those two gentlemen?

A. As far as I know.

Q. At that time, Ian Troup was president of Upsher-Smith, was he not?

A. Correct.

Q. And Ken Evenstad was the chairman of Upsher-Smith at that time?

A. I believe chairman and CEO.

Q. Was he also the principal shareholder?
A. We have a privately held company, from his family.
Q. During this meeting with Servier, did Dr. Arnaud indicate that after the meeting Servier was going to have to do an internal evaluation of the clinical data that Upsher had provided?
A. Well, under Next Steps here, it says, "Servier must internally evaluate the clinical data."
Q. Is that your recollection?
A. Yes, everyone needs to digest the information. They can't make any decisions right on the spot.
Q. Dr. Arnaud didn't commit to a time for getting back to Upsher-Smith to indicate whether or not Servier was interested in the license, did he?
A. That's what it says here, "They did not commit to a timetable for indicating to Upsher-Smith their interest."
Q. And any follow-up communications between Servier and Upsher-Smith after this meeting would have gone through Ms. O'Neill. Is that right?
A. That's correct.
Q. During this meeting, Upsher-Smith representatives and Servier representatives didn't discuss the structure of compensation for a Niacor-SR

license, did you?

A. I don't know, that wasn't my focus. I was focused on the science side of the presentation. Ms. O'Neill focused on the business side.

Q. You don't recall, though, any discussion of the structure of compensation for a Niacor-SR license, do you?

A. I don't recall specifically, no.

Q. Servier in the course of this meeting didn't make any monetary offer for a license of Niacor-SR, did they?

A. I don't recall. That wasn't my focus of the presentations.

Q. Let's move now, if we could, to the meeting that you and Ms. O'Neill had with -- is it pronounced Esteve?

A. Yes.

Q. That was one of the Spanish companies -- pharmaceutical companies, correct?

A. Correct.

Q. You and Ms. O'Neill were the only representatives of Upsher-Smith at the meeting with Esteve, right?

A. Correct.

Q. Did you personally, again, present the safety

and efficacy information at that meeting?

A. Yes, I did.

Q. Do you recall how long you spent on safety and efficacy in that meeting?

A. I don't recall the amount of time it takes to make the presentation. It always varies depending on the number of questions, whether you use extra slides. I just don't know.

Q. In these four meetings with the European companies, when you were going through the safety and efficacy information, did you orally present the slides about safety and efficacy that were in that packet?

A. I would put the slide up on the overhead, and there was a printed handout that they were given, and then I had my own extra backup slides that if a question came up, I could put an overhead up, and that wasn't included in their handouts.

Q. But the slides that you did project, did you talk through the points on those slides?

A. Yes.

Q. And there was an opportunity for the European pharmaceutical company representatives to ask you questions?

A. Yes.

Q. At the meeting with Upsher-Smith, Esteve was

represented by Dr. Miro?

A. Yes.

Q. He was the medical director in Esteve's international division, was he not?

A. I don't know his exact title.

Q. At the meeting, Dr. Miro questioned whether Niacor-SR provided sufficient advantages over immediate release niacin, did he not?

A. I don't recall that specifically. I'd have to see the notes to make sure of that.

MS. BOKAT: May I approach the witness, Your Honor?

JUDGE CHAPPELL: Yes, you may. Oh, excuse me, Ms. Hertzman, would you be able to call up CX 868, please.

MS. HERTZMAN: Sure.

MS. BOKAT: Did you want a copy, Your Honor?

JUDGE CHAPPELL: I can see it, thanks.

BY MS. BOKAT:

Q. CX 868 is a memorandum of your meeting with Esteve, is it not?

A. Yes.

Q. That's again from you and Ms. O'Neill to Mr. Troup and Mr. Evenstad?

A. Yes.

Q. Dr. Miro discussed during the meeting whether Niacor-SR provided sufficient advantages over immediate release formulations of niacin, did he not?

A. He also discussed the side effects of flushing and whether Niacor-SR provided sufficient advantages over IR formulations from the memo here.

Q. Is that your recollection?

A. I don't have a complete recollection of that.

Q. Do you assume -- well, let me ask you first, who prepared CX 868, the minutes of the meeting with Esteve?

A. Ms. O'Neill.

Q. Do you assume that she was trying to be accurate in summarizing that meeting for Mr. Troup and Mr. Evenstad?

MR. CARNEY: Objection, calls for speculation.

MR. RAOFIELD: Same objection.

JUDGE CHAPPELL: Sustained.

BY MS. BOKAT:

Q. Did Dr. Miro indicate that after the meeting, he was going to review the clinical information Upsher had provided with his international group?

A. Under Next Steps, it says, "Dr. Miro will review the clinical information with the International group," and secondly it says, "Forward data to the

Clinical and Medical Department, if the International review is favorable."

Q. So, was Dr. Miro going to review the clinical information that Upsher had provided with his International Group?

A. That's what it states here, yes.

Q. If the International Group drew a favorable conclusion about a Niacor-SR license, was Dr. Miro going to forward the data on to the Clinical and Medical Department?

MR. CARNEY: Objection, calls for speculation.

MS. BOKAT: I don't think it calls for speculation, Your Honor. According to this memo, it was discussed during the meeting.

JUDGE CHAPPELL: I'll sustain the objection as the question's phrased. You'll need to restate it.

BY MS. BOKAT:

Q. Mr. Halvorsen, do you recall during the meeting with Esteve Dr. Miro indicating that if the review of his International Group was favorable, he would forward the clinical data to his Clinical and Medical Department?

A. I do not specifically recall.

Q. Do you recall him talking about forwarding information to his Marketing Department?

A. I do not specifically recall.
Q. Do you recall whether Dr. Miro indicated when he would get back to Upsher-Smith?
A. I don't recall the specifics, but it was greater than a month.
Q. Esteve didn't offer any amount of compensation for a Niacor-SR license during this meeting, did they?
A. I don't recall.
Q. You also, you and Ms. O'Neill, met with representatives from Lacer. Is that right?
A. Yes.
Q. Is that another Spanish pharmaceutical manufacturer?
A. Yes, it is.
Q. Lacer had several representatives at the meeting, did they not?
A. I believe they did. I don't remember specific names.
Q. Do you remember the head of their medical department being in attendance?
A. I don't remember the specific individuals that were there.
Q. Do you remember the managing director of their pharmaceutical division being there?
A. I don't remember the specific individuals who

were there.

Q. Do you remember the head of their licensing department being there?

A. I don't recall the specific individuals who were there.

Q. Maybe I can give you a document that will help your recollection.

May I approach the witness, Your Honor?

JUDGE CHAPPELL: Yes.

MS. BOKAT: Would you like a paper copy, Your Honor?

JUDGE CHAPPELL: No, thanks, it's up.

BY MS. BOKAT:

Q. Is CX 880 a memorandum of your meeting with Lacer?

A. The first page is.

Q. Is the first page a memorandum from you and Ms. O'Neill?

A. Yes.

Q. That memorandum is addressed to Mr. Troup and Ken Evenstad, is it not?

A. Correct.

Q. Who prepared this memorandum?

A. Ms. O'Neill.

Q. Having looked at it, do you recall who attended

the meeting from Lacer?

A. I don't recall the specific names or the titles, no.

Q. So, looking at the document doesn't refresh your recollection at all?

A. No, I just recall that it was someone from their medical department and that's about the extent of my recall on specific individuals.

Q. Do you have any reason to think that Ms. O'Neill's memorandum is inaccurate about who attended?

A. No.

Q. Did Ms. O'Neill show you this memorandum before she sent it to Mr. Troup and Mr. Evenstad?

A. I don't recall.

Q. Did Ms. O'Neill show you the memorandum of your meeting with Esteve before she sent it to Mr. Troup and Mr. Evenstad?

A. I don't recall.

Q. Did Ms. O'Neill show you the memorandum summarizing the meeting with Servier before she sent it to Mr. Troup and Mr. Evenstad?

A. I don't recall.

Q. You personally did a presentation on efficacy and safety of Niacor-SR to the representatives of Lacer during the meeting, did you not?

A. Correct.

Q. Was Lacer going to have a physician review the clinical data after the meeting?

A. Under the Next Steps here, it says, "Lacer will have an expert physician review the clinical data under a secrecy agreement."

Q. Was Lacer also going to determine the number and type of patients for whom Niacor-SR therapy would be appropriate?

A. It says here on the memo, "From this review, Lacer will make a 'go/no go' decision as well as a determination of the number and type of patients that would be appropriate for Niacor-SR therapy."

Q. Lacer didn't offer a specific amount of money for a license of Niacor-SR during this meeting, did they?

A. I don't recall.

MS. BOKAT: May I approach the witness, Your Honor?

JUDGE CHAPPELL: Yes.

MS. BOKAT: Would you like a copy, Your Honor?

JUDGE CHAPPELL: Is it on the ELMO?

MS. BOKAT: I think it's on the monitor.

JUDGE CHAPPELL: I don't need it.

BY MS. BOKAT:

Q. Is CX 881 a memorandum summarizing the meeting with Pierre Fabre?
A. Yes, it is.
Q. Is that memorandum from you and Ms. O'Neill?
A. Yes.
Q. Who prepared the memorandum?
A. Ms. O'Neill.
Q. It's addressed to Mr. Troup and Ken Evenstad. Is that right?
A. That is correct.
Q. Did you see the memo before it went forward to Mr. Troup and Mr. Evenstad?
A. I don't recall.
Q. Who attended the meeting with Upsher-Smith on behalf of Pierre Fabre?
A. The four individuals listed here on this page.
Q. So, that's Salomon Azoulay, was he one?
A. Yes, according to this page.
Q. Was he a medical doctor?
A. Yes, that's what it says here.
Q. Was he also director of clinical research for Pierre Fabre?
A. That's what it says on this memo, yes.
Q. Who else attended?
A. According to this memo, there is a licensing

manager, a planning and coordination director and a project evaluation manager.

Q. The licensing manager is Marc Pennacino?

A. Correct.

Q. Is the planning and coordination director Andre-Claude Feniou?

A. Yes.

Q. Was he holder of a doctorate in chemistry?

A. That's what it states on this memo, yes.

Q. And the last attendee, was that Mike Briley?

A. Yes.

Q. Does he also hold a doctorate?

A. It says here he has a Ph.D.

Q. You and Ms. O'Neill attended this meeting, I take it.

A. Yes.

Q. Did you personally present safety and efficacy information to the representatives of Pierre Fabre?

A. Yes, I did.

Q. Was that safety and efficacy presentation similar to the one you had made for the other three pharmaceutical companies -- other three European pharmaceutical companies?

A. Correct.

Q. The memo indicates there was also a

presentation on the patent status of Niacor-SR. Do you recall who made the presentation on the patent status?

A. Ms. O'Neill.

Q. Do you know whether she had prepared that presentation in advance?

A. I think it was part of the handout. There was a -- one or two slides on the O'Neill patent and one on the Evenstad patent.

Q. Had she made a patent presentation at the other three meetings with European pharmaceutical manufacturers?

A. I can't say from my direct recall, but that was part of the handout for all four companies.

Q. Was there some discussion during the meeting with Pierre Fabre about whether the patent would issue in Europe?

A. It says here on the memo, "The basis of their discussions was whether the patent would issue in Europe."

Q. Which patent was that?

A. I don't know.

Q. Was there a patent pending before a European nation?

A. There could have been. I don't recall. That wasn't my area of expertise.

Q. During the meeting with Pierre Fabre, did you have the impression that they already had information about Kos' Niaspan product?

A. Yes.

Q. Did the representatives of Pierre Fabre ask about the incidence of elevation of LFTs in the studies for Niacor-SR?

A. It states here, "It was apparent they had reviewed our previous package on Niacor-SR and asked intelligent perceptive questions on the incidence of elevation in LFTs."

Q. Did they also express concern over the high incidence of elevation in LFTs with the 2000 milligram dose of Niacor-SR?

A. It states here that, "Although they expressed concern over the high incidence at the 2000 milligram dose, there was a good discussion on the appropriate use of niacin in combination with HMG-CoAs and use of niacin at lower doses."

Q. So the answer to my question is yes?

A. Based on that sentence, I guess the answer is yes.

Q. You did discuss with the representatives of Pierre Fabre the possible payment structure for a Niacor-SR license, did you not?

A. I did not.
Q. I beg your pardon?
A. I did not.
Q. Did someone else during that meeting?
A. Ms. O'Neill.
Q. Do you recall the representatives of Pierre Fabre being concerned about the size of up-front and milestone payments in a license for Niacor?
A. No, I do not.
Q. Do you recall the representatives of Pierre Fabre making a reference to unreasonable payments of $50 million?
A. I do not.
Q. Do you recall either yourself or Ms. O'Neill suggesting milestone payments of at least $5 million rather than the $50 million?
A. I do not.
Q. Do you recall either you or Ms. O'Neill suggesting that Upsher-Smith would consider taking greater royalty payments in lieu of up-front payments?
A. I do not recall.
Q. Was Pierre Fabre going to continue evaluating Niacor-SR after your meeting?
A. I believe so, yes.
Q. As of the time of the meeting, had they already

assigned a project manager to the license or potential license of Niacor-SR?

A. I don't recall. I'd have to look through the memo here.

Q. Well, if you look at the second page, which bears the Bates number USL 11826, there's a heading Next Steps?

A. Um-hum.

Q. And then the paragraph after that might help you.

A. The second sentence says, "It was encouraging that they appeared to be immediately working with the project manager to define the tasks and responsibilities for the additional information."

Q. Do you recall that?

A. I recall they were very positive on the product. Specifically a project manager, I do not recall.

Q. Did Pierre Fabre indicate that they would need until the end of June to get back to Upsher-Smith?

A. I don't recall specifically. They needed one or more months. I don't know.

Q. The representatives of Pierre Fabre during this meeting didn't offer an amount of compensation for a Niacor-SR license, did they?

A. I don't recall.

Q. Mr. Halvorsen, at all four of these meetings with European pharmaceutical companies, the European company had a scientist or a physician or a pharmacist in attendance, did they not?

A. I'd have to look back through all of the list of attendees to answer that question.

Q. Take your time.

JUDGE CHAPPELL: Ms. Bokat, how much more do you have?

MS. BOKAT: May I add the caveat that I am not very good at time estimates?

JUDGE CHAPPELL: Okay.

MS. BOKAT: With that caveat, I would guess, if I could finish the last couple of questions here and then maybe have five minutes to confer with my colleagues, then I could probably wrap this up in 20 to 30 minutes.

JUDGE CHAPPELL: Okay, we are going to take a lunch break as soon as you finish this line of questioning.

THE WITNESS: Could I have the question repeated, please?

BY MS. BOKAT:

Q. Yes. At the meetings with these four European

pharmaceutical companies, did they have at least a scientist or a physician or a pharmacist in attendance?

A. Yes.

Q. During the meetings, none of these four European companies offered a specific amount of compensation for a Niacor-SR license, did they?

A. I don't recall.

MS. BOKAT: Your Honor, that concludes this line of questioning.

MR. CARNEY: Your Honor, could we suggest a short lunch break, as this witness will be unavailable for the next two weeks, and we would like to try to finish him up today? I understand you have something else this afternoon.

JUDGE CHAPPELL: Right. We are going to -- it's about -- it's almost 1:30. We will break until 2:00.

MR. RAOFIELD: Your Honor, may I just clarify for the record the one point we had left outstanding, the exhibit that I had intended to introduce?

JUDGE CHAPPELL: Okay.

MR. RAOFIELD: It turns out that that exhibit for the record is SPX 250 and has already been admitted. So, I withdraw my motion or my effort to --

JUDGE CHAPPELL: Okay.

MR. RAOFIELD: Thank you.

JUDGE CHAPPELL: We will recess until 2:00.

(Whereupon, at 1:28 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(2:00 p.m.)

JUDGE CHAPPELL: Ms. Bokat, you may continue.

In the event this witness isn't finished before 3:00, my hearing is not going to take I don't think more than an hour, so the parties have the option of taking a break and coming back. I'm definitely not trying to encourage longer cross or redirect. With that -- I just wanted to let you know that is an option.

MS. BOKAT: Your Honor, may I approach the witness, please --

JUDGE CHAPPELL: Yes.

MS. BOKAT: -- with CX 962? Would you like a paper copy, Your Honor?

JUDGE CHAPPELL: I don't need it if it's on the ELMO.

BY MS. BOKAT:

Q. Mr. Halvorsen, have you seen documents like CX 962 before?

A. Yes, I have.

Q. Would you describe what these are, please?

A. These are monthly project updates.

Q. And is this a series of monthly project updates for Niacor-SR?

A. It looks like it, yes.

Q. Would you turn, please, to the third page of that exhibit, which bears the Bates number USL 13253. Does it appear from that that by January 15th, 1998, the project for an NDA for Niacor-SR had been put on hold?

A. For Upsher-Smith's NDA, yes.

Q. Is that also your recollection?

A. Yes.

Q. And as of early January 1998, at Upsher-Smith, was there only minimal activity that would continue on Niacor-SR?

A. No.

Q. That's wrong?

A. No, if you look below that, you'll see that all study reports will be completed and that this represents a significant amount of resource hours.

Q. So, where it says, "Action: Only minimal activity will continue," that was wrong?

A. No, it depended on what department was actually working on the project. The clinical department was going full forward.

Q. These monthly project updates, are they for a particular department within Upsher-Smith?

A. No, it's for -- done by our project management

group.

Q. So, it's for the entire project?

A. It's for multiple departments done by project management.

Q. You talked earlier in the day about a meeting in 1998, it may have been in March, where you were informed that Schering was not going to go forward with the Niacor project?

A. Yes.

Q. Who attended that meeting?

A. I recall two individuals, Mark Robbins and Ian Troup. I don't remember who the others were.

Q. And yourself.

A. Including myself, yes.

Q. And you think there were some other people there as well?

A. I believe so, but I don't recall who.

Q. Were they all Upsher-Smith people?

A. Yes.

Q. No one from Schering?

A. No.

Q. Who told you that Schering wasn't going forward with Niacor-SR?

A. I don't remember the individual.

Q. Do you believe it was either Mr. Robbins or Mr.

Troup?

A. I don't recall who it was.

Q. Did anyone tell you who at Schering had informed Upsher-Smith that Schering was not going forward with Niacor-SR?

A. I don't recall.

Q. You mentioned earlier a visit from someone at Schering to Upsher-Smith's facilities. That was in connection with the pentoxifylline product, was it not?

A. I don't believe so.

Q. What product was it about?

A. It was for our cholestyramine product, Prevalite.

Q. But it wasn't for Niacor-SR?

A. I don't believe so.

Q. The PK study that the FDA asked for in February or March of 1997 for Niacor-SR, that PK study wasn't a reason for Upsher-Smith dropping the NDA on Niacor-SR, was it?

A. No.

Q. You mentioned that you spoke with James Audibert about the indications for Niacor-SR compared to the indications for Niaspan.

A. I don't believe I said that.

Q. Did you talk to Mr. Audibert about the

indications that Niacor-SR would have?

A. I don't recall.

Q. Mr. Audibert asked about the clinical investigators from the Niacor-SR studies, right?

A. Correct.

Q. Mr. Audibert made that inquiry in August of 1997. Is that right?

A. According to the document that we reviewed, yes. I don't know the specific dates.

Q. Do you have any reason to think the date in that document was wrong?

A. No.

Q. When Mr. Audibert asked for the studies from Niacor-SR, that was in August of 1997?

A. I don't recall the specific dates. That memo showed that he was following up from our earlier conversations.

Q. But that was after Schering and Upsher-Smith had entered into their agreement, right?

A. I believe so, but as I said earlier, I don't recall the exact dates of communications.

Q. Prior to June 17th, 1997, the date of the Schering-Upsher agreement, Mr. Audibert hadn't asked to see any of those hundreds of boxes worth, the 30 pallets worth of boxes on Niacor-SR studies that Upsher

had, had he?

A. Can you repeat that question?

Q. Maybe I can try and rephrase it, make it a little clearer.

Prior to June 17th, 1997, the date of the Schering-Upsher agreement, Mr. Audibert hadn't asked to see any of those hundreds of boxes of documents at Upsher about Niacor-SR, had he?

A. They weren't in boxes at that point. They were as case report forms, and part of the data management process, they were using those documents actively to complete all of the data entry, the statistical pieces, making sure all of that was clean. So, they weren't in that form at that point in time.

Q. Did he ask to see that data before June 17th, 1997, even if it wasn't in boxes yet?

A. He wouldn't have asked for that kind of information.

Q. You and Mr. Carney talked earlier today about telephone conferences with ClinTrials. Is that right?

A. ClinTrials, NovaTech Sciences and CSR Consultants, yes.

Q. Those were weekly telephone conferences?

A. Yeah, we tried to have them weekly, maybe missed one or two weeks.

Q. Were the telephone conferences still ongoing in the second half of 1997?

A. Yes.

Q. Did Schering participate in any of those teleconferences?

A. No.

Q. Did Upsher invite Schering to participate in any of those teleconferences?

A. No.

Q. Did Upsher -- I'm sorry, did Schering ask to participate?

A. No.

Q. Over what period of time were you personally involved in searching for a license partner for Niacor-SR?

A. That's really hard to put a number on it. I started working on the presentation and I put the clinical safety and efficacy presentation together, either myself or with others helping, I don't know how long that took. It had to be several months to get all of that together.

Q. You and Ms. O'Neill spent more time in the search for a licensing partner than anyone else at Upsher-Smith, did you not?

MR. CARNEY: Objection, foundation.

THE WITNESS: I don't know.

JUDGE CHAPPELL: I'll overrule it. He can answer that.

MS. BOKAT: Do you need the question read back, sir?

THE WITNESS: Sure.

(The record was read as follows:)

"QUESTION: You and Ms. O'Neill spent more time in the search for a licensing partner than anyone else at Upsher-Smith, did you not?"

THE WITNESS: I can't answer that. I don't know what time others spent.

BY MS. BOKAT:

Q. And you and Ms. O'Neill attended more meetings with potential licensees on Niacor-SR than anyone else at Upsher-Smith, did you not?

A. Again, I can't answer that, because I can't speak for others, so I don't know.

Q. Well, you and Ms. O'Neill were the only people at the four meetings with the European companies, right?

A. That is correct.

Q. And you, Ms. O'Neill and Ms. Freese were at the Searle meeting?

A. Correct.

Q. Was there anyone else from Upsher at that meeting?

A. We had two representatives for Upsher that we brought in, Dr. Claude Drobnes and Dr. Greg Brown.

Q. But Lori Freese, Dr. Brown and Dr. Drobnes weren't at any of the European meetings.

A. That is correct.

Q. So, you and Ms. O'Neill went to more meetings than they did.

A. Yes.

Q. And no one else from Upsher was at any of those five meetings, the four European partners and Searle, right?

A. Those specific meetings, correct.

Q. And you personally made presentations at all five of those meetings, correct?

A. That is correct.

Q. And did Ms. O'Neill make presentations at all five of those meetings?

A. I believe so.

Q. You didn't meet with anyone from Schering about Niacor-SR before June 17th, 1997, did you?

A. Not that I can recall.

Q. You didn't help prepare anyone at Upsher for meetings with Schering-Plough about Niacor-SR, did you?

A. Not specifically for Schering-Plough, no.

Q. You didn't attend any of the negotiation meetings between Schering-Plough and Upsher-Smith, did you?

A. No, I did not.

Q. Was your involvement in the agreement between Upsher-Smith and Schering-Plough limited to reviewing how the names of the products appeared in the agreement?

A. Yes.

MS. BOKAT: Could I have just a minute, Your Honor?

JUDGE CHAPPELL: Yes.

MS. BOKAT: Thank you.

(Counsel conferring.)

MS. BOKAT: Thank you, Your Honor, that concludes my cross examination.

JUDGE CHAPPELL: Redirect?

MR. CARNEY: Yes, Your Honor, just briefly.

REDIRECT EXAMINATION

BY MR. CARNEY:

Q. Now, if you could turn just for a second to what is marked CX 962, I think it's the pamphlet you've got there, and then on the -- what is the third page of the document, it's that January 15th, 1998 Niacor

product update Ms. Bokat was asking you about.

Do you see where it says, "Issues, 1, Issues, project put on hold," and below it there's another 1 that says, "All study reports must be submitted to the FDA," and then, "This represents a significant amount of resource hours."

Did that refer to work internally or externally at Upsher -- in connection with Niacor-SR?

A. Both.

Q. And when you say "both," that's --

A. Both the internal resources from Upsher-Smith, the Clinical Research Department, and then the CROs that we were working with on the final study reports in the ISS/ISE. So, ClinTrials, NovaTech and CSR Consultants.

Q. And those conference calls that we looked at earlier, were they going on at this time?

A. Yes, they were.

Q. And point 2 below that, "Analytical Method Development. Action: MDS Harris will complete method work through method validation."

What's that referring to?

A. That was one of the two laboratories that we had competing against each other. MDS Harris was still working on getting a method completed.

Q. And do you recall what was spent on getting that method validation done at that time?

A. We spent a total of $400,000 to complete all of the method work.

Q. Who do you report to at Upsher-Smith?

A. Dr. Mark Robbins.

Q. And do you provide any reports or updates to anyone else at Upsher-Smith?

A. Yes, Dr. Robbins had left the company for about a year and a half time frame, and I reported directly to Mr. Troup.

Q. And as part of your job responsibilities, were you providing updates in the spring of 1997 regarding Niacor-SR?

A. Yes, I was.

Q. And did you provide such updates prior to June 17th?

A. Yes, I did.

Q. Do you know if your superiors had taken an interest in Niacor-SR?

A. Absolutely --

MS. BOKAT: Objection, Your Honor. I think this goes well beyond the scope of cross.

MR. CARNEY: Your Honor, a lot of the questions were relating to Dr. Halvorsen's involvement with the

Schering negotiations and the status of Niacor-SR, and this is going to who knew what about Niacor-SR in that time period at Upsher-Smith.

JUDGE CHAPPELL: Well, I can remember he was asked about Niacor on direct and cross, so I'll overrule it.

MR. CARNEY: Could you repeat the question, please?

(The record was read as follows:)

"QUESTION: Do you know if your superiors had taken an interest in Niacor-SR?"

THE WITNESS: Absolutely.

BY MR. CARNEY:

Q. In your testimony when Ms. Bokat was asking you questions, you mentioned that the FDA was very pro-niacin. What did you mean by that?

A. The FDA really liked niacin, and they wanted to have a sustained release niacin product out in the marketplace. It goes back to early meetings we had in 1992 and in 1994, and as time went on, I found out when Kos had -- was given two indications that they hadn't even asked for, it really shows me that FDA was very pro-niacin.

Q. I want to shift topics and move to the European meetings. At those meetings, the representatives of

the other companies asked you questions about the Niacor-SR product?

A. Yes, they did.

Q. And I think you testified that some of those questions were about Lp(a)?

A. Yes.

Q. Is that right?

Immediate release versus sustained release niacin?

A. Correct.

Q. Questions regarding flushing?

A. Correct.

Q. Did any of those questions surprise you?

A. No.

Q. Were those concerns that you would have expected to have heard at such a meeting?

A. Oh, yes. Those were topics that you would expect from any group looking at the product and listening to my presentation.

Q. And it's correct that they were evaluating your product at that time, Niacor-SR?

A. Yes.

Q. In those meetings, were you evaluating them at all?

A. Yes.

Q. How were you evaluating them?

A. We wanted to see who would be interested in the product, and you can gauge that by the amount of questions and the amount of background information that they've prepared for your presentation, and then also just looking at what type of markets they were currently in. If they were in the hyperlipidemia market already, they were familiar with the marketplace so they would be able to jump right into it.

Q. And then shifting topics again, Mr. Raofield showed you an e-mail from Marge Garske from August of '98 referring to archiving. Do you know who did the internal archiving at Upsher-Smith of the Niacor documents?

A. Marge Garske was our lead person, and then Gina McClure and Tiea Crane were working on individual studies, and we put all of that through -- Marge actually came up with a system to archive it.

Q. And do you know how long it took them to do that archiving?

A. Months.

Q. Why did it take that long?

A. Because there was that much documentation. We had all of our internal documentation, all of the ClinTrials documentation, the NovaTech and the CSR

Consultants documentation, as well as investigational information.

Q. And did those three individuals have other responsibilities at that time?

A. Their primary activities were to work on the Niacor-SR activities and to get everything boxed up and cleaned up. They may have had one other project to take up a small amount of their time.

Q. There's no archiving department or records department at Upsher-Smith, is there?

A. No, there's not. We do it ourselves.

MR. CARNEY: No further questions, Your Honor.

MR. RAOFIELD: Nothing for Schering, Your Honor.

JUDGE CHAPPELL: Anything further?

MS. BOKAT: Just a few.

JUDGE CHAPPELL: You may.

MS. BOKAT: Thank you, Your Honor.

RECROSS EXAMINATION

BY MS. BOKAT:

Q. Mr. Halvorsen, you mentioned that the FDA was pro-niacin.

A. Yes.

Q. Niaspan had the application for the NDA filed ahead of Niacor-SR, correct?

A. Correct.

Q. And Niaspan I think you said was approved in July of 1997?

A. Correct.

Q. So, that was going to be approved in advance of Niacor-SR.

A. Correct.

Q. And that would provide a Niaspan -- a sustained release Niaspan to the market.

A. Yes.

MS. BOKAT: Nothing further, Your Honor. Thank you.

JUDGE CHAPPELL: Thank you, Mr. Halvorsen, you're excused.

Who's next?

MR. CURRAN: Your Honor, given our understanding that we were going to conclude at 2:30-2:45 today, that's it for the day as far as arranged witnesses.

JUDGE CHAPPELL: Who's next Tuesday?

MR. CURRAN: Who's next on Tuesday?

MR. NIELDS: Mr. Audibert, Your Honor.

JUDGE CHAPPELL: How many more witnesses do you have?

MR. NIELDS: That's an issue that we will be

addressing over the weekend, we hope, Your Honor. There are some things --

JUDGE CHAPPELL: So, the number you would give me now is the biggest number possible, right?

MR. NIELDS: All right, the biggest number possible Ms. Shores is going to pass on to me. In other words, people on our witness list who have not yet testified is the number you're about to get.

JUDGE CHAPPELL: Okay. And for Upsher?

MR. NIELDS: Twelve, Your Honor.

JUDGE CHAPPELL: Is that for Schering?

MR. NIELDS: Schering.

JUDGE CHAPPELL: Okay.

MR. CURRAN: Your Honor, I don't have the exact number, but it's not realistic, because we are re-examining how many witnesses are necessary, and we will shorten our list.

JUDGE CHAPPELL: Did your list grow, Mr. Nields? I thought it was ten -- I thought it was ten the last time I asked.

MR. NIELDS: I'm afraid that I have to concede that I did say -- you said with -- you gave me some margin of error, and I said in the neighborhood of ten, and you are correct, that it did grow.

JUDGE CHAPPELL: Okay.

MR. NIELDS: And it's because of the margin -- I hope you'll give me the margin of error as the explanation.

JUDGE CHAPPELL: Okay, although you're much better predicting how long your examination is going to take.

MR. NIELDS: Apparently so.

JUDGE CHAPPELL: And I think Mr. Kades was off by four minutes yesterday, you can let him know that, on his prediction.

Then we are adjourned until -- does anybody want to work Monday?

MS. BOKAT: I'll be courageous and say we could use a day outside the courtroom on Monday. Also, it may be hard to get people in and out of this building on a federal holiday.

JUDGE CHAPPELL: That's true. I just thought I'd throw it out there. So, we will take the holiday off, at least from trial. So, we're adjourned until Tuesday morning at 9:30. Thanks.

(Whereupon, at 2:35 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N  O F  R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: FEBRUARY 15, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 2/18/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N  O F  P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE